Staff Summary

Please note that this accompanying summary information is included to only supplement the original documentation, and assist the Committee members in their thorough review of the source documentation provided in the site survey, desk review or case investigation packet.

Case Description: CADN self-reported staff incorrectly assigned ABO O to a donor who had undergone mass transfusion protocol whose multiple ABO typings reported mixed results and discrepancies. CADN consulted the Organ Center and donor hospital lab, placed detailed notes regarding ABO in the DonorNet donor highlights section, and subsequently completed organ allocation based on the ABO O assignment. All centers were aware of the ABO discrepancy before accepting the organ and had reviewed ABO results in DonorNet.

The heart, kidney/pancreas, kidney, and liver were allocated to four different centers, who all transplanted ABO O recipients. Post-transplant, it became clear that the donor was actually ABO B and all recipients had received an ABO incompatible transplant. Subsequently, all recipients, except for the liver recipient, experienced graft rejection and graft removal.

Possible Action (based on historical MPSC action in similar cases):

- Close with no action based on self-reporting
- Notice of Noncompliance for Policy 2.6.A

MPSC History:

- Feb 2021: Kidney laterality error, closed for self-reporting*
- Nov 2019: Notice of Noncompliance for kidney laterality error*
- July 2019: Notice of Noncompliance for shipping organs with insufficient ice on two separate occasions

*Self-reported events

Survey Information: A routine on site survey of the OPO occurred on March 13-14, 2018. The OPO had a clinical score of 100 percent and some administrative errors. The MPSC reviewed the results of the survey at its meeting in October 2018 and closed the review with no action.

OPO Volumes:

Year	Donors Recovered	Organs Recovered
2018	318	1,141
2019	411	1,394
2020	411	1,383
2021	195*	673*

*As of July 14, 2021

Historical MPSC Actions: The MPSC would typically close a self-reported case with no action if the member does not have a history of this noncompliance and addressed the issue through its corrective action plan. While the member self-reported this event and meets these requirements, this issue

represents a potential risk to patient safety and requires subcommittee review. The MPSC may consider closing the case or issuing a Notice of Noncompliance.

Reviewer Comments:
Reviewer 1: At a minimum I think a notice of non-conformance is in order. Perhaps the full committee should discuss this case at it resulted in graft loss for multiple patients.

Reviewer 2: Notice of non-compliance at minimum. Noted clear communication and disclosure of ABO discrepancies with accepting transplant centers. It looks as though they did not follow their policy (Infectious Disease/ABO Testing Manual - 2.2.2.3.1) on how to list discrepant ABO for samples resulting in O and B; according to their policy, the donor should have been run as a B donor versus an O donor. The policy effective date was prior to the incident. Did the OPO provide any updates on if ABO genotyping is available and logistically possible? Also one clarifying question within their CAP; who is considered a Qualified Health Care Professional who will make independent determinations of blood type? Would one of these Qualified Health Care Professionals include someone with blood banking/center background or transfusion medicine?

Reviewer 3: I agree with minimum of notice of non-compliance after review of the packet of information. Also support discussion at committee level.

Issue Involves: Donor Network West (CADN)
Issue Reported by: University of California San Francisco Medical Center (CASF)
Issue Reported by: California Pacific Medical Center – Van Ness Campus (CAPM)
Self-Report received from: CADN
Issue Reported by: University of California San Diego Medical Center (CASD)

Issue: CASF reported this event through the OPTN Improving Patient Safety Portal. **CAPM**, **CADN**, and **CASD** subsequently reported the event as well.

CADN assigned ABO O to a donor who had undergone mass transfusion protocol whose multiple ABO typings reported mixed results and discrepancies. Organ allocation was completed based on the ABO O assignment.

The heart, kidney/pancreas, kidney, and liver were allocated to four different centers, who all transplanted ABO O recipients. Post-transplant, it became clear that the donor was actually ABO B and all recipients had received an ABO incompatible transplant. Subsequently, all recipients, except for the liver recipient, experienced graft rejection and graft removal.

UNOS Incident Handling spoke to all four receiving centers as part of this investigation. All centers were aware of the ABO discrepancy before accepting the organ and had reviewed ABO results in DonorNet. All centers were confident that the donor was ABO O, except for **CASU**.

CASU, the liver center, was concerned that the donor was actually ABO B. However, their liver recipient was ill and in need of transplant, so **CASU** proceeded as if the donor *was* ABO B and plasmapheresed their recipient to accept an ABO B liver. **CASU** believed that if the donor were ABO O, the liver recipient would be fine; but if the donor were actually ABO B, the plasmapheresis would allow the recipient to still accept the transplant.

Relevant OPTN Policy:
2.6.A <u>Deceased Donor Blood Type Determination</u>: "The host OPO must include a process to address conflicting or indeterminate primary blood type results..."

Relevant Correspondence:
Communication with CADN - received on December 24, 2020
Communication with CADN - received on December 27, 2020
Inquiry to CADN - sent on December 31, 2020
Response from CADN - received on January 14, 2021
Notification letter to CADN - sent on January 27, 2021
Additional Response from CADN - received on February 4, 2021

Member Response:

CADN reported:

<u>Donor Admission Timeline and ABO Typing</u>
12/13/20

- The donor was admitted to an outside hospital and given mass transfusion protocol, approximating two blood volumes. There was no pre-transfusion blood for ABO typing.

- ABO typing #1 resulted as ABO O, but the blood bank verbally told **CADN** "real type is unknown, but based of weak back-type...may have been B." **CADN** did not receive the written documentation of this result until after transplant.

12/14/20

- A second ABO typing was attempted, but cancelled due to the mass transfusion.
- ABO typing #2 initially resulted as invalid, but was then changed to ABO O. The red blood cells typed as O, however the serum typed as a weak B. Donor hospital blood bank staff added additional serum to testing, resulting in ABO O.

12/17/20

- **CADN's** Clinical Procurement Coordinator (CPC) was notified that a donor hospital Physician's Assistant had reported that the donor was possibly ABO B.

12/20/20

- ABO typing #3 was completed on a "qualified" sample. The sample initially returned as cancelled, due to being unable to obtain a valid result, then was called invalid, then resulted as ABO O. The red blood cells typed as O, however the serum typed as a weak B. Donor hospital blood bank staff added additional serum to testing, resulting in ABO O. This sample would eventually, post-transplant, result as ABO B when re-tested by **CADN's** lab and by a receiving center.

12/21/20

- VRL, the testing lab for **CADN**, explained that the most recent sample had a "mixed field result" and they were sending it to their main lab for confirmation using donor-derived DNA. Results were expected in two to three days.
- The **CADN** CPC, Organ Allocation Coordinator (OAC), and Clinical Operations Manager (COM) reviewed all the existing ABO results "which all resulted as ABO = O" and were "consistent." This review included the first blood draw from the day of admission.
- Two **CADN** COMs discussed that the first two ABO results were from blood draws occurring during/near the mass transfusion protocol.
- A **CADN** CPC, COM, and OAC discussed ABO results. The OAC was unsure what the word "invalid" on the results meant. The CPC stated that the donor's "red cells are recognized as 'O' but his serum has not made up its mind what it wants to be so it keeps reading invalid. They keep adding more serum and it results as O." A **CADN** Family Resource Coordinator (FRC) confirmed the donor's family did not know the donor's ABO.
- A **CADN** CPC called the UNOS Organ Center to discuss the case. The Organ Center advised **CADN** follow OPTN policies regarding hemodilution assessment, and to add text in DonorNet donor highlights describing the mixed results. Following this conversation, the CPC reported to others that "according to UNOS we are in policy."
- A **CADN** CPC spoke to the donor hospital trauma lab about the "invalid" results. The CPC stated that "the sample was read as O and serum as B. Noted this as odd because they added serum which resulted as O." The CPC noted that ABO results are "inconclusive" in the donor EMR.
- **CADN** placed the following text into DonorNet donor highlights: "Pt is s/p MTP (see blood products page for quantity) with ABO resulting O+ after x2 type and screens

drawn at the donor hospital. No ABO or blood samples were drawn on initial admission to hospital prior to MTP being initiated. Hospital ABO continues to result inconclusive. ID samples did not result an ABO. Per hospital trauma blood bank, when typing the pt, the red cells type as O however the serum types as B. The staff has to add more serum in order for the sample to result; The result is O+."

Allocation and Acceptance of Organs

12/22/20

- A kidney center declined a directed donation offer due to "too much concern" for donor ABO accuracy.
- A second kidney center declined an offer because "it seems unclear what the [donor] blood type actually is."
- **CASF** expressed concern that so many centers were declining organs, and initiated a direct consultation with the donor hospital blood bank; after this conversation, **CASF** accepted the kidney with no concerns for ABO accuracy.
- Hours before the donor OR, **CASU**, who had accepted the heart, expressed concerns about donor ABO accuracy and requested a 48-72 hour delay for additional ABO testing. **CADN** declined the request due to confidence in the ABO, two accepting centers with blood bank expert consults, lack of available ICU space, and donor family concerns for length of case. **CASU** declined the heart, which **CASD** subsequently accepted.
- **CAPM**, the K/P center, also expressed concern about donor ABO accuracy. **CAPM** consulted with **CASF** and felt comforted that the ABO was accurate.

12/23/20

- Procurement was completed with all accepting centers being fully informed of the ABO typing discrepancy, and having had opportunity to review ABO source documents and ask **CADN** questions.

Post-Transplant

- About 6 hours after crossclamp, **CASD** notified **CADN** that the heart recipient was demonstrating graft rejection, and they were concerned this was due to an ABO incompatible transplant. **CADN** reached out to the other centers to check the status of their recipients:
    - **CASU** (liver) stated that the liver "can tolerate ABO incompatibility and the recipient was doing well."
    - **CAPM** (K/P), who had not yet started transplant, inquired about the status of the liver recipient, and was informed that the recipient was well. After internal discussion, **CAPM** chose to proceed with transplant.
    - **CASF** reported that their kidney recipient was "doing fine."
- Approximately six hours after notification of the heart's recipient graft rejection, **CADN** received documentation confirming the donor was ABO B. This result came from the blood sent out to the main VRL lab on 12/21/20 to use donor-derived DNA for testing. **CADN** communicated this result to all accepting centers.
- The next day, **CAPM** also provided documentation of the donor being ABO B, as they had re-tested blood at their lab.

Causes of ABO Tying Error

- **CADN's** procedures did not "define how to address invalid or cancelled tests. The two final source documents verifying the ABO as O Positive were not recognized as discrepant."
- **CASF's** confidence in the donor ABO after discussion with the donor hospital blood bank "reinforced" **CADN's** confidence in the accuracy of the ABO results.
- **CADN** felt they had three separate ABO results, and had followed OPTN and internal policies for determining ABO.

CADN corrective actions:

- As an immediate containment plan, **CADN** emailed staff reminding them that clinical leadership should review any ABO result that is less than conclusive, and that a cancelled test is an inconclusive test.
- ABO genotyping will be performed for all of the following situations (pending research on the availability of testing and logistical issues):
    - Mass transfusion with no pre-transfusion sample;
    - ABO result comments suggest a different underlying blood type;
    - Discrepancy between forward and reverse typing;
    - Invalid or inconsistent testing.
- If the discrepancy cannot be resolved, or if there is lingering doubt about accuracy, the donor will be listed as ABO AB.
- Policy was revised to:
    - Redefine "indeterminate" to explicitly include cancelled or invalid tests;
    - Require that at least one result come from a non-donor hospital lab;
    - Require ABO genotyping on any donor transfused with O blood who does not have pre-transfusion blood available (pending research on the availability of testing and logistical issues);
    - Require two Qualified Health Care Professionals, one of whom must be a Clinical Operations Manager, to make independent determinations of blood type;
    - Require a hard stop in discrepancy cases that must involve the **CADN** CMO, who will then guide the process of determining blood type; this change involves the CMO at the *beginning* of a discrepant ABO case and prevent the donor OR from proceeding until discrepancies or concerns are resolved.
- Mandatory training sessions were held with staff where a new verification process was introduced that requires a pre-allocation huddle where transfusion history is discussed, and all ABO typings are finalized. The training curriculum now includes scenario training and effectiveness checks.

SFC OPTN Hearing Exhibit A.1

[redacted]

Choose an application

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Help

Improving Patient Safety

Safety Situation [redacted]

The goal of the Improving Patient Safety system is to collect information about safety related incidents occurring system-wide, in order to increase organ utilization and decrease the morbidity and mortality of transplant pati

What is a Safety Situation?
A situation or activity that affected or could have affected patient safety.

What to report:

- Any patient safety situation
- Any other situation that causes a safety concern from a transplantation, donation, and/or quality perspective.

Please report such situations in a timely manner.

Below you will find the most current information for situation 101928. You can complete the following tasks on this page:

- Access a printer-friendly version of this safety situation
- Add resolution information

Situation Information

Reporting Institution: * **CASF-Univ of CA San Francisco Med Ctr-Transplant Hospital(Member)**

Type of Safety Event (Choose all categories and subcategories that are applicable): *

- ☐ Communication
- ☐ Data Entry
- ☐ Transportation
- ☐ Packaging/Shipping
- ☐ Labeling
- ☐ Recovery Procedure/Process
- ☐ Transplant Procedure/Process
- ☒ Testing
  - ☒ ABO
    - ☐ ABO error or discrepancy
    - ☐ ABO misinterpretation
    - ☐ ABO subtyping error or discrepancy
    - ☐ ABO subtyping misinterpretation
    - ☒ Blood transfusion caused misleading results
    - ☐ Switched samples
    - ☐ Switched source documentation
    - ☐ Inadequate sample for testing
    - ☐ Other (please describe in the description field below)
  - ☐ HLA
  - ☐ Infectious Disease
  - ☐ Other (please describe in the description field below)
- ☐ Organ Allocation/Placement
- ☐ Other (please describe in description field below)

The Issue reported involves the following (choose all categories that are applicable): *

- ☒ **Recipient/Candidate**
  - **Waitlist ID:** **No Waitlist ID:** ☒
  - **SSN:** * [redacted]
- ☐ **Donor Organ/Extra Vessels**
- ☐ **Other (please describe in the description field below)**

Date Event Occurred: * 12/23/2020

Detailed Description of the Event: * Kidney from donor [redacted] from a GSW victim became available. Due to GSW, donor underwent massive transfusion protocol. ABO typing returned 2 O results and 1 B, UCSF Tx Services consulted our transfusion service for guidance and accepted the organ. Center that accepted the heart contacted OPO to report immediate failure, and center that accepted the other kidney and pancreas reported organ necrosis and removal. OPO contacted UCSF to report potential incompatible transplant. Our patient is currently stable and is in the process of receiving an kidney ultrasound and anti-B titers.

SFC OPTN Hearing Exhibit A.1

[redacted]

Choose an application

(/PatientSafety/Default.aspx?CTXT=0zAAoKjDBdSbcyae89NBXCoMmWeX4hhUt0hEYz1hHlvKMCIBPqZQyw%3D%3D)

Help

Improving Patient Safety

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Below you will find the most current information for situation 101929. You can complete the following tasks on this page:

- Access a printer-friendly version of this safety situation
- Add resolution information

Situation Information

Reporting Institution: * **CAPM-California Pacific Med Ctr-Transplant Hospital(Member)**

Type of Safety Event (Choose all categories and subcategories that are applicable): *

- [ ] Communication
- [ ] Data Entry
- [ ] Transportation
- [ ] Packaging/Shipping
- [ ] Labeling
- [ ] Recovery Procedure/Process
- [ ] Transplant Procedure/Process
- [x] Testing
  - [x] ABO
    - [x] ABO error or discrepancy
    - [x] ABO misinterpretation
    - [ ] ABO subtyping error or discrepancy
    - [ ] ABO subtyping misinterpretation
    - [ ] Blood transfusion caused misleading results
    - [ ] Switched samples
    - [ ] Switched source documentation
    - [ ] Inadequate sample for testing
    - [ ] Other (please describe in the description field below)
  - [ ] HLA
  - [ ] Infectious Disease
  - [ ] Other (please describe in the description field below)
- [ ] Organ Allocation/Placement
- [ ] Other (please describe in description field below)

The Issue reported involves the following (choose all categories that are applicable): *

- [x] **Recipient/Candidate**
  Waitlist ID: [redacted] **No Waitlist ID:** [ ]
- [ ] **Donor Organ/Extra Vessels**
- [ ] **Other (please describe in the description field below)**

Date Event Occurred: * 12/23/2020

Detailed Description of the Event: * Donor Network West offered "O" blood type donor [redacted] with history of multiple transfusions to "O" recipients. Our Kidney Pancreas recipient candidate ID [redacted]) suffered hyperacute rejection and the organs were removed. Suspect donor was actually a "B" donor. Multiple other transplants performed at several different institutions; at least some experiencing similar outcomes. Appropriate allocation of this donor with no pretransfusion sample available would have been to ABO AB recipients.

Has a root cause analysis (RCA) been completed? * ( ) **Yes** ( ) **No** (•) **In Progress**

SFC OPTN Hearing Exhibit A.1

[redacted]

Choose an application

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Help

Improving Patient Safety

Safety Situation [redacted]

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A situation or activity that affected or could have affected patient safety.

What to report:

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- Any other situation that causes a safety concern from a transplantation, donation, and/or quality perspective.

Please report such situations in a timely manner.

Below you will find the most current information for situation 101930. You can complete the following tasks on this page:

- Access a printer-friendly version of this safety situation
- Add resolution information

Situation Information

Reporting Institution: * **CADN-Donor Network West-Independent OPO(Member)**

Type of Safety Event (Choose all categories and subcategories that are applicable): *

- ☐ Communication
- ☐ Data Entry
- ☐ Transportation
- ☐ Packaging/Shipping
- ☐ Labeling
- ☐ Recovery Procedure/Process
- ☐ Transplant Procedure/Process
- ☒ Testing
  - ☒ ABO
    - ☐ ABO error or discrepancy
    - ☐ ABO misinterpretation
    - ☐ ABO subtyping error or discrepancy
    - ☐ ABO subtyping misinterpretation
    - ☒ Blood transfusion caused misleading results
    - ☐ Switched samples
    - ☐ Switched source documentation
    - ☐ Inadequate sample for testing
    - ☐ Other (please describe in the description field below)
  - ☐ HLA
  - ☐ Infectious Disease
  - ☐ Other (please describe in the description field below)
- ☐ Organ Allocation/Placement
- ☐ Other (please describe in description field below)

The Issue reported involves the following (choose all categories that are applicable): *

- ☐ **Recipient/Candidate**
- ☒ **Donor Organ/Extra Vessels**

Donor ID associated with the event: * [redacted]

Did this event involve the entire donor or were only specific organs involved? * Entire Donor

Organ Type

- ☐ **Right Kidney**
- ☐ **Left Kidney**
- ☐ **Dual/En-bloc Kidney**
- ☐ **Pancreas**

- Pancreas Segment 1
- Pancreas Segment 2
- Liver
- Liver Segment 1
- Liver Segment 2
- Intestine
- Intestine Segment 1
- Intestine Segment 2
- Heart
- Right Lung
- Left Lung
- Double/En-bloc Lung
- Extra Vessel(s)

Did this safety situation cause or contribute to:

The non-recovery of organ(s)? * No

The discard of any organ(s)? * No

A delay (prolonged ischemic time) for any organ(s) transplanted? * No

- Other (please describe in the description field below)

Date Event Occurred: * 12/23/2020

Detailed Description of the Event: * CADN was informed on 12-23-2020 that heart recipient from Donor A[redacted] was doing poorly. The donor received multiple transfusions. ABO testing was ultimately determined to be O+, however, questions of validity and mis-matched reverse typing was recognized. Testing scenario was described in Donor Highlights and donor was listed as type O. Subsequent testing indicates donor was type B. All transplant centers have been notified.

Has a root cause analysis (RCA) been completed? * Yes No In Progress

Please specify additional details regarding the RCA: In progress

Please upload any relevant attachments:

Contact Information

Who at your institution should UNOS contact about this case?

First Name: * [redacted] **Last Name:** * [redacted]

Phone contact (Enter at least one): *

Office: * [redacted] ext. **Pager/beeper:** ext.

Mobile: [redacted] ext. **Other:** ext.

Email: * [redacted]

Other contact info:

UNOS Only

Reported by: [redacted]

Initial UNOS Action

Date: * 12/24/2020 **Staff member:** [redacted]

Status: * In process **Urgency:** * Medium

Category: * Major

Potential policy violation: YES NO

Committee notification? YES NO

Type of Safety Event (Choose all categories and subcategories that are applicable):

- Communication
- Data Entry
- Transportation
- Packaging/Shipping
- Labeling
- Recovery Procedure/Process
- Transplant Procedure/Process
- Testing
- Organ Allocation/Placement
- Other (please describe in description field below)

Attachments

Choose File No file chosen

Maximum File Size 20MB

SFC OPTN Hearing Exhibit A.1

[redacted]

Choose an application

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Help

Improving Patient Safety

Safety Situation [redacted]

The goal of the Improving Patient Safety system is to collect information about safety related incidents occurring system-wide, in order to increase organ utilization and decrease the morbidity and mortality of transplant pati

What is a Safety Situation?
A situation or activity that affected or could have affected patient safety.

What to report:

- Any patient safety situation
- Any other situation that causes a safety concern from a transplantation, donation, and/or quality perspective.

Please report such situations in a timely manner.

Below you will find the most current information for situation 101931. You can complete the following tasks on this page:

- Access a printer-friendly version of this safety situation
- Add resolution information

Situation Information

Reporting Institution: * **CASD-UCSD Medical Center-Transplant Hospital(Member)**

Type of Safety Event (Choose all categories and subcategories that are applicable): *

- [x] Communication
  - [ ] Hand off Error
  - [x] Miscommunication of donor test results
  - [ ] Miscommunication of recipient/candidate results
  - [ ] Change in test results not reported
  - [ ] Misinterpretation of test results
  - [x] Delayed communication
  - [ ] Reliance on electronic instead of verbal communication
  - [ ] Inaccurate/insufficient donor or (organ/extra vessels) information
  - [ ] Inaccurate/insufficient candidate/recipient information
  - [ ] Missing documentation
  - [ ] Increased risk (or high risk) status of donor
  - [ ] Patient not informed adequately (or not informed at all)
  - [ ] Other (please describe in the description field below)
- [ ] Data Entry
- [ ] Transportation
- [ ] Packaging/Shipping
- [ ] Labeling
- [ ] Recovery Procedure/Process
- [ ] Transplant Procedure/Process
- [x] Testing
  - [x] ABO
    - [x] ABO error or discrepancy
    - [x] ABO misinterpretation
    - [ ] ABO subtyping error or discrepancy
    - [ ] ABO subtyping misinterpretation
    - [x] Blood transfusion caused misleading results
    - [ ] Switched samples
    - [ ] Switched source documentation
    - [ ] Inadequate sample for testing
    - [ ] Other (please describe in the description field below)
  - [ ] HLA
  - [ ] Infectious Disease

SFC OPTN Hearing Exhibit A.1

☐ Other (please describe in the description field below)

☐ Organ Allocation/Placement

☐ Other (please describe in description field below)

The Issue reported involves the following (choose all categories that are applicable): ✳

☒ **Recipient/Candidate**

Waitlist ID: [redacted] **No Waitlist ID:** ☐

☒ **Donor Organ/Extra Vessels**

Donor ID associated with the event: ✳ [redacted]

Did this event involve the entire donor or were only specific organs involved? ✳ Entire Donor

Organ Type

☐ **Right Kidney**

☐ **Left Kidney**

☐ **Dual/En-bloc Kidney**

☐ **Pancreas**

☐ **Pancreas Segment 1**

☐ **Pancreas Segment 2**

☐ **Liver**

☐ **Liver Segment 1**

☐ **Liver Segment 2**

☐ **Intestine**

☐ **Intestine Segment 1**

☐ **Intestine Segment 2**

☐ **Heart**

☐ **Right Lung**

☐ **Left Lung**

☐ **Double/En-bloc Lung**

☐ **Extra Vessel(s)**

Did this safety situation cause or contribute to:

The non-recovery of organ(s)? ✳ No

The discard of any organ(s)? ✳ No

A delay (prolonged ischemic time) for any organ(s) transplanted? ✳ No

☐ **Other (please describe in the description field below)**

Date Event Occurred: ✳ 12/23/2020

Detailed Description of the Event: ✳ Transplant recovery specialist received a call from CADN (OPO) coordinator at 20:30 on 12/22/20 about a heart offer that was backed out by CASU 1 hour prior to donor OR. The OPO administrator on call gave CASD an open offer for a heart if we could get to the donor OR ASAP (expected within 4 hours). The surgeon and the heart transplant on call coordinator were notified via text and phone call about the open offer. Transplant surgeon and the cardiologist reviewed the offer and the decision was made to accept the heart for patient [redacted] who was at sequence [redacted]. Upon arrival to the donor recovery OR, the OPO coordinator advised the CASD recovery team of the inconclusive ABO on the first result from 12/14/20. They reassured the recovery team that they had 2 confirmation ABOs from the donor hospital that was blood type O and the sample was non-hemodiluted. The CASD transplanting surgeon was called in the presence of the recovery surgeon and OPO coordinator by the recovery specialist to discuss the ABO results. The decision was made to proceed with the recovery of the donor heart as there was 2 confirmed ABOs from a non-hemodiluted sample. The cross clamp time was 0324 on 12/23/20. Heart transplant initially went as planned with new transplanted heart beating on its own but minutes after biventricular dysfunction as well as myocardial edema was noted on TEE. Complication documented as hyperacute graft rejection. The transplanting surgeon recommended to reach out to CADN allocation line and check on the status of the organs transplanted at other centers. It was confirmed by CADN that they did not receive any report of graft dysfunction from other transplant centers. CASD heart team initiated communication with the other transplant surgeons where the kidney/pancreas and liver was transplanted. CASD surgeon spoke to the surgeon from CAPM and was notified that the k/p was in acute rejection post-transplant. The call was also made to the liver surgeon at CASU and she told us that they were aware of the ABO discrepancy and they had accepted the organ for their patient who was listed to accept an ABO incompatible organ. They had their patient plasmapheresed and consented for non-ABO compatible transplant. CASU surgeon also mentioned that she advised CADN OPO that the donor should be listed as B and to notify all centers prior to acceptance of organ from this donor. CASU surgeon mentioned that the heart and isolated kidney offers were declined at their center for ABO result inconsistency. After our conversation with transplant surgeons at other centers we spoke to the OPO clinical manager. We requested OPO to do due diligent search on previous hospital admission, request ABO of parents and investigate other option for ABO confirmation (buccal swab, femur, spinal cord). We received a call back from OPO administrator on call at 17:59 notifying that they had 2 results back. The CAPM center who received the K/P did confirmatory ABO and got a weak B on their archive sample. They were also advised that at 16:55 that got results from VRL lab in Denver confirming the donor ABO as B positive. He also mentioned that the VRL result from the original send out was indeterminate. They opted to allocate the organs with the 2 hospital ABO test result. The patient is on VA ECMO on max support and is relisted as status1. CASD transplant administrator reached out to CADN administrator to review the timeline and received donor blood type confirmation report as B positive. The heart transplant leadership team made notified.

Has a root cause analysis (RCA) been completed? ✳ ○ **Yes** ○ **No** ◉ **In Progress**

Please specify additional details regarding the RCA: Investigation initiated as soon as the recipient had complication of hyperacute graft rejection in the OR.

Please upload any relevant attachments:

File Name	Date Uploaded	Delete
ahis321-final abo vrl denver.pdf (DownloadAttachment?name=101931_SAFS_ahis321-final%20abo%20vrl%20denver.pdf&CTXT=MRl59OnNbtbzIF07rj6xfUxwS9VuPzl5A5bhuwR6Jcovn1gwMv%2FN7g%3D%3D)	12/24/2020	

VRL | Eurofins Pre-Transplant Testing

Final Report

Order Details		Ordering Professional	
DNW Referral ID	[redacted]	2341 - Donor Network West - OPO	
UNOS#	[redacted]	[redacted]	
Name	[redacted]	[redacted]	
DOB	[redacted]		
Gender	M		

Request / Accession	R-122120-00002
Received	12/20/2020 18:10
Final Report	12/23/2020 16:32
Report Generated	12/23/2020 16:32
Time Zone	Pacific Standard Time

Results

Test	Completed	Results	Ref. Range
ABO/Rh	12/23/2020 16:32	**B Positive**	

Sample Reference(s)

Collection Time Zone: Pacific Standard Time

VRL Sample ID	Type	Collected	Test(s)
[redacted]	Plasma - EDTA	12/20/2020 11:45	1405

Donor Type: *Pre-Mortem* ***Transfusion:*** *Post-Transfusion*

Test Reference(s)

Code	Name	Methodology Description
1405	ABO/Rh	ABO typing performed using BioRad reagents.

Laboratory: *VRL Eurofins*
[redacted]
CLIA #: [redacted]
Laboratory Director: [redacted]

[redacted]

Subject: [EXTERNAL] CADN Immediate Action Regarding [redacted]

Hi [redacted]

We are instructing our organ clinical leadership as follows:

> Effective immediately, any ABO test that indicates anything other than a conclusive result, or is in any way inconsistent with other ABO testing; must be reviewed by organ program clinical leadership.
>
> Please reply to acknowledge receipt.

Our early review of the event, in context of our existing procedure, indicates this will prevent recurrence in the short term as we continue our detailed assessment.

Any input is welcomed.

Thank you,

[redacted]

[redacted]

DonorNetworkWest.org

[redacted]

[redacted]

Subject: [EXTERNAL] RE: CADN Immediate Action Regarding [redacted] ABO
Attachments: Infectious Disease Testing Manual.pdf

Hi [redacted]

Attached is our protocol.

Hi [redacted]

Please see the attached section from our manual relating to testing and resolving ABO discrepancies.

We have amended our previous interim instruction as follows: "All ABO tests must be considered when determining a donor's blood type. If any test indicates anything other than a conclusive result (including cancellation), or is in any way inconsistent with other ABO testing; all results must be reviewed by organ program clinical leadership and must follow SE-M-001, Section 2.2, Guidelines for Handling Conflicting Primary Blood Type Results. This includes testing by an outside (non-hospital) lab"

We feel this will ensure all results are considered, conflicts are resolved per procedure including the use of an outside lab, and donors are listed conservatively based on all testing. We are open to additional action if warranted.

Thank you,

[redacted]

-----Original Message-----

[redacted]

Subject: RE: CADN Immediate Action Regarding [redacted] ABO

[redacted] by Sunday night could you please send me your protocols for resolving indeterminate ABO, and what change in that protocol is involved in the description below?

Sent with BlackBerry Work (www.blackberry.com)

[redacted]

Subject: [EXTERNAL] CADN Immediate Action Regarding [redacted] ABO

Hi [redacted]

We are instructing our organ clinical leadership as follows:

Effective immediately, any ABO test that indicates anything other than a conclusive result, or is in any way inconsistent with other ABO testing; must be reviewed by organ program clinical leadership.

Please reply to acknowledge receipt.

Our early review of the event, in context of our existing procedure, indicates this will prevent recurrence in the short term as we continue our detailed assessment.

Any input is welcomed.

Thank you,

[redacted]

[cid:image007.png@01D45CAD.8A8F6D20]<https://www.donornetworkwest.org/>

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1.4.3 TISSUE PROCESS

1.4.3.1 Procurement of Specimen

1.4.3.1.1. Once blood is obtained, placed into the appropriate tubes, and labeled, the blood is then placed in the recovery cooler until tissue procurement is complete.

1.4.3.2 Processing and Shipment/Delivery

Processing of the specimen prior to packaging and method of delivery to the testing lab are dependent on the geographic location of the donor.

1.4.3.2.1. Recovery at DNWest Norris Canyon Facility or Recovery Locations with Return to Norris Canyon

- Processing of the specimens by the RC is not required. The specimens are to be placed in a biohazard bag and the completed requisition is to be placed in the pocket of the bag. The specimen will be hand delivered to the testing lab.

1.4.3.2.2. Satellite Recovery Locations Requiring Shipment

- Upon return to the satellite office, specimens will be spun and placed in aliquot tubes and labeled. The processed specimens will be packaged in wet ice shippers. Multiple donor specimens can be placed in a single wet ice shipper (approximately 3 donors or the equivalent of 12 tubes).
- Redding and Reno locations: once packaged and ready for shipment to the testing lab, the technician will arrange for pickup either via FedEx or DNWest driver.
- Fresno location: once packaged and ready for shipment to the testing lab, the RC will place the package in the FedEx pickup area. Daily pickup by FedEx will occur at the designated times.
  - DNWest drivers can be utilized when appropriate.
  - QUICK service can be utilized when FedEx pick-up is not available in a timely manner.

1.4.4 VRL-EUROFINS SPECIMEN PROCESSING

1.4.4.1 Stat testing runs will be started 1.5 – 2 hours following receipt of the samples or sooner if there is sufficient advance notice of specimen arrival.

1.4.4.1.1. Additional testing requests can be made by the DC via email after consultation with the COM and/or onsite coordinator.

1.4.4.2 Testing specimens can be held for up to 48 hours only, or must be aliquotted and frozen within 48 hours, to facilitate the full testing panel.

1.4.4.3 Non-stat testing runs will be on a production cycle and will occur at 0600, 1400, and 0000.

1.4.4.4 Fail over / power outage equipment battery backup is good for 30 minutes. This should enable VRL to safely remove samples from equipment and ship to their backup testing facility.

2.0 ABO & SUBTYPE TESTING

2.1 ABO AND SUBGROUP TESTING AND VERIFICATION

2.1.1 INTRODUCTION AND OVERVIEW

2.1.1.1 The purpose of this section is to describe the DNWest policy which mandates the determination of two separate blood group determinations on all potential organ donors in compliance with UNOS/OPTN policy.

2.1.1.2 This procedure applies to all potential organ donors.

2.1.1.3 Allocation of organs will be based on the donor's primary blood type without consideration of subtyping in the following instances:

2.1.1.3.1. Pretransfusion specimens are not available

2.1.1.3.2. The laboratory is unable to interpret results

2.1.1.3.3. Subtyping results are discrepant

- Hospital ABO subtype (if applicable)
- All Infectious Disease testing lab subtypes

2.1.1.3.4. Allocation has begun prior to subtype results being confirmed

2.1.2 RESPONSIBILITIES

Qualified Health Care Professionals (QHCP) - Organ Program staff responsibility to:

2.1.2.1 Obtain and verify two separate determinations of the donor's blood type (and subtype, if applicable) prior to match run.

2.1.2.2 Use the source documents to enter and verify the donor's blood type (and subtype, if applicable) in the DNWEST ELECTRONIC DONOR RECORD and UNET.

2.1.2.3 Verify online the donor blood type (and subtype, if applicable).

Note: this must be done by an individual other than the person initially entering the data.

2.1.2.4 Document the double verification of a donor's blood type (and subtype, if applicable) and have the documentation available for review by the United Network for Organ Sharing (UNOS).

2.1.2.5 Convey the blood group to UNOS and to transplant center personnel.

2.1.3 ATTACHMENTS

- 4.1 ABO SUBTYPE REQUIREMENTS AND RESULTS ALGORITHM

2.1.4 PROCESS

The DNWest on-site coordinator shall be responsible for obtaining two separate ABO determinations, and subtype if indicated, that meet the following requirements:

2.1.4.1 OPTN/UNOS Guidelines: Subtyping is required when the following three conditions are met:

2.1.4.1.1. The donor is more than 3 years old;

2.1.4.1.2. The donor's ABO blood type is A (AB is optional); and

2.1.4.1.3. Both subtype determinations can be made on pre-transfusion samples (transfusion of blood or blood products in the previous 120 days can affect results; however, plasma or platelets will not affect the determination of the A subtype).

2.1.4.2 Two separate samples for ABO and subtyping must be taken on two separate occasions, defined as: one draw and then another draw after 5 minutes or more of elapsed time.

2.1.4.2.1. **Note:** All available typing and subtyping results must be assessed and found to be equivalent (e.g. hospital results, first laboratory result, second laboratory result).

2.1.4.2.2. **Note:** For all blood type A donors, documentation in the ELECTRONIC DONOR RECORD will be completed indicating either subtyping was completed, or the reason why it could not be completed.

2.1.4.2.3. **Note:** Historical blood type results can be used for one of the typings if source documentation of these results is available.

2.1.4.3 Documentation of the laboratory initial and confirmatory tests will be maintained in the ELECTRONIC DONOR RECORD.

2.1.4.4 Upon receipt of the ABO typing, the DC will register the donor in the DonorNet system.

2.1.4.5 The DC will attach the UNET Donor Summary Screenshot to the ELECTRONIC DONOR RECORD. The on-site coordinator will verify the UNET Donor Summary Screenshot.

2.1.4.6 Prior to initiating DonorNet match runs, a second DNWest coordinator, who is a QHCP, will verify the donor's ABO and subtype (if applicable) from two separate sources, drawn on two separate occasions, and submitted as separate samples using source documents in DonorNet.

2.1.4.6.1. Verification will be documented in the ELECTRONIC DONOR RECORD.

2.1.4.6.2. If a discrepancy exists between the source documents, an additional sample for ABO determination will be obtained and tested at the donor hospital, or other designated testing site, in an attempt to resolve the discrepancy.

- Guidelines for Handling Conflicting Primary Blood Type Results in section 2.2 will be used in an attempt to resolve the discrepancy.

2.1.4.7 Upon recovery team arrival and prior to incision, the on-site coordinator, who is a QHCP, will review the entire donor record and will verify the donor ID, ABO and subtype (if applicable), and organs to be recovered (including laterality) using source documents and acceptable sources, with each lead recovery surgeon/personnel.

2.1.4.8 The VERIFICATION OF ABO AND OR TIME OUT CHECKLIST will be signed by the on-site coordinator and each lead recovery surgeon/personnel.

2.1.4.9 A copy of page one of the signed VERIFICATION OF ABO AND OR TIME OUT CHECKLIST form with the ABO Verification section completed will be:

2.1.4.9.1. Included in the donor record that accompanies each organ;

2.1.4.9.2. Attached to the ELECTRONIC DONOR RECORD; and

2.1.4.9.3. Attached in DonorNet.

2.2 GUIDELINES FOR HANDLING CONFLICTING PRIMARY BLOOD TYPE RESULTS

2.2.1 INTRODUCTION AND OVERVIEW

2.2.1.1 The purpose of this section is to ensure recipient safety by establishing a consistent method for addressing and resolving conflicting primary blood type results which may occur when the donor has been subjected to blood transfusions that result in sero conversion.

2.2.2 PROCESS

2.2.2.1 Should two separate primary blood type results conflict, the following steps should be taken:

2.2.2.1.1. Initiate an additional blood type test at the donor hospital in an attempt to resolve the discrepancy.

- A primary blood type conducted prior to any transfusion should be used as the standard for matching.
- Historical blood type results can be used for one of the typings if source documentation of these results is available.

2.2.2.1.2. Obtain an additional typing specimen and send it to an outside lab for testing.

2.2.2.1.3. If no blood transfusions were administered and a discrepancy between the two primary results still exists, two additional separate samples will be drawn at two separate times and submitted for typing as two separate specimens to two separate labs.

2.2.2.2 If unable to resolve the discrepancy, a huddle to establish a plan will be held with the CMO, COM, DC and onsite coordinator. An Administrator may be contacted as needed.

2.2.2.3 The plan can include the following guidelines for resolving hemodilution.

2.2.2.3.1. When efforts to resolve the discrepancy have been exhausted, the following match run sequence should take place with the more restrictive blood type to be utilized for the match run. A pre-transfusion specimen should be used as the standard for the match run. Situations in which this would occur include blood transfusions administered via massive transfusion protocol prior to, and/or in between, blood draws.

- A blood type and O blood type = match run on A blood type.
- B blood type and O blood type = match run on B blood type.
- A blood type and B blood type = match run on AB blood type.
- A blood type and AB blood type = match run on AB blood type.
- B blood type and AB blood type = match run on AB blood type.
- O blood type and AB blood type = match run on AB blood type.
- Should the A subtype be in conflict, then the donor will be considered to be A1 or A1B as appropriate.

2.2.2.4 Document and communicate the plan as follows:

2.2.2.4.1. Document the plan in the progress notes of the electronic donor record.

2.2.2.4.2. Verbally communicate the plan to all receiving transplant centers.

2.2.2.4.3. Include a statement in Donor Highlights section of DonorNet. Samples:

- Donor with UNOS ID WXYZ123 has an undetermined ABO after multiple testing attempts. We have conferred with our Medical Director and decided to identify the donor as type X. This is the most restrictive type indicated by the incongruent results. Recipients matching the blood type as listed should be compatible regardless of how the results are interpreted.
- Donor with UNOS ID WXYZ123 has an undetermined ABO after multiple testing attempts. We have conferred with our Medical Director and opted to identify the donor as type AB to minimize risk of incompatibility given recipients on the match should be AB and "universal recipients" with immunologic compatibility to any ABO.

2.2.2.4.4. Print multiple copies of the statement for use in the Operating Room. Attach copies to ABO verification paperwork (e.g. ABO VERIFICATION AND OR TIME OUT CHECKLIST and VERIFICATION OF LABELING AND PACKAGING form) and include copies with source ABO documents that accompany each organ.

2.2.2.4.5. Attach results of every ABO test to DonorNet and include results of every ABO test with each organ.

[redacted]

Subject: [EXTERNAL] RE: CADN Immediate Action Regarding [redacted] ABO

Hi [redacted]

Upon review of our process, we see a few possible gaps:

- 2.1.4.2.1. says "All available typing and subtyping results must be assessed and found to be equivalent (e.g. hospital results, first laboratory result, second laboratory result)". We think we may not have recognized cancelled tests as a "result", and in general not considered all results.
- 2.1.4.6.2 indicates resolving discrepancy by testing at donor hospital "or" other designated testing site. This conflicts with the following bullet that indicates using the guidelines, which indicate testing at hospital and an outside lab.
- 2.2.2.2 indicates a huddle if discrepancies cannot be resolved

The interim instructional statement says:

- "All ABO tests must be considered when determining a donor's blood type. If any test indicates anything other than a conclusive result (including cancellation), or is in any way inconsistent with other ABO testing; all results must be reviewed by organ program clinical leadership and must follow SE-M-001, Section 2.2, Guidelines for Handling Conflicting Primary Blood Type Results. This includes testing by an outside (non-hospital) lab"

We believe this statement emphasizes the need to consider all results as stated in 2.1.4.2.1; it addresses 2.1.4.6.2 by requiring a result from an outside lab, and it indicates a huddle much earlier in the process (when conflicting results are identified).

Again, please recognize we are still in the discovery process.

Thank you,

[redacted]

Original Message

[redacted]

Subject: RE: CADN Immediate Action Regarding [redacted] ABO

Thank you - this has been received.

Can you describe what makes this interim process different from the usual way ABO discrepancies were resolved? What I will be asked about is how this is a change in the process, and I need to be sure I am articulating that clearly.

[redacted]

[redacted]

-----Original Message-----
[redacted]
Subject: [EXTERNAL] RE: CADN Immediate Action Regarding [redacted] ABO

Hi [redacted]

Attached is our protocol.

Hi [redacted]

Please see the attached section from our manual relating to testing and resolving ABO discrepancies.

We have amended our previous interim instruction as follows: "All ABO tests must be considered when determining a donor's blood type. If any test indicates anything other than a conclusive result (including cancellation), or is in any way inconsistent with other ABO testing; all results must be reviewed by organ program clinical leadership and must follow SE-M-001, Section 2.2, Guidelines for Handling Conflicting Primary Blood Type Results. This includes testing by an outside (non-hospital) lab"

We feel this will ensure all results are considered, conflicts are resolved per procedure including the use of an outside lab, and donors are listed conservatively based on all testing. We are open to additional action if warranted.

Thank you,

[redacted]

[redacted]
Subject: RE: CADN Immediate Action Regarding [redacted] ABO

[redacted] by Sunday night could you please send me your protocols for resolving indeterminate ABO, and what change in that protocol is involved in the description below?

Sent with BlackBerry Work (www.blackberry.com) _____

[redacted]
Subject: [EXTERNAL] CADN Immediate Action Regarding [redacted] ABO

Hi [redacted]

We are instructing our organ clinical leadership as follows:

Effective immediately, any ABO test that indicates anything other than a conclusive result, or is in any way inconsistent with other ABO testing; must be reviewed by organ program clinical leadership.

Please reply to acknowledge receipt.

Our early review of the event, in context of our existing procedure, indicates this will prevent recurrence in the short term as we continue our detailed assessment.

Any input is welcomed.

Thank you,

[redacted]

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[redacted]

OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

December 31, 2020

VIA SECURE EMAIL

[redacted]
Chief Executive Officer
Donor Network West
[redacted]

Dear [redacted]

The United Network for Organ Sharing (UNOS) serves as the Organ Procurement and Transplantation Network (OPTN) under contract with the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services. Under that contract, UNOS staff review reported or identified patient safety and/or public health-related concerns associated with organ donation and transplantation occurring within the OPTN.

UNOS' Member Quality staff screen all reports to determine whether the [redacted] suggests a risk or threat to patient safety or public health. Often additional information is needed from the involved OPTN member(s) to finalize the assessment of threat. If the [redacted] is assessed as both time-sensitive and serious, this department will alert UNOS and/or OPTN Membership and Professional Standards Committee (MPSC) leadership and, under that direction, work with OPTN member(s) to alleviate the threat.

UNOS' Member Quality Department staff also screen all reports to determine if there is a possible violation of OPTN bylaws or policies associated with the [redacted] Again, additional information is typically needed from OPTN member(s) involved in order to complete the assessment.

We are currently reviewing the blood type determination and reporting for donor [redacted] by Donor Network West (CADN). Our preliminary analysis indicates that CADN determined the donor's ABO to be O and allocated organs as such. The donor was actually ABO B.

We are contacting you to obtain a complete understanding of what occurred. We appreciate as much detail as you can provide. Any information you provide that suggests a potential policy or bylaw violation, or which may pose a threat to transplant or donor patient health or public safety may be referred for review by UNOS leadership, including the MPSC, and in some cases the OPTN Board of Directors.

Please address the following issues related to the ABO determination/reporting for this donor and subsequent organ allocation:

- Provide a detailed timeline and review of the ABO determination for this donor including:
  - The draw date/time and result date/time of every sample sent for or used to determine donor ABO (including cancelled tests, invalid results, etc.);
  - Documentation for each of these blood draws and results, including the result(s) that found the presence of ABO B in donor serum;
  - Complete transfusion records and hemodilution calculations;
  - A detailed summary of all discussions related to the donor's ABO results and concerns for validity of the results. Include when these discussions occurred and a detailed list of the individuals who participated;
  - A description of all factors considered when CADN decided to allocate organs as ABO O.

- Provide a root cause analysis or post-case review of the ABO determination and reporting.

- Provide a detailed timeline and review of the communication with evaluating and accepting centers, including:
  - What centers were told regarding the donor's ABO before procurement, especially in regards to the mixed O and B results;
  - Concerns communicated to CADN by evaluating or accepting centers regarding the validity of the reported ABO;
  - When CADN first heard that there were recipient issues that suggested rejection, and when and how CADN communicated this information to other recipient centers;
  - When CADN first heard that a confirmed ABO B result was discovered;
  - What communication CADN had with centers after the ABO B result was discovered.

- Provide your Standard Operating Procedures and/or policies for donor ABO determination and reporting, and process for addressing conflicting or indeterminate primary blood type results.

- Provide any quality assurance measures, and/or tools or resources used to determine and report donor ABO, particularly any relevant to situations when the donor's blood is drawn post-transfusion, if applicable.

- What corrective actions have been implemented or are planned as a result of this event? If corrective actions include revisions to existing documents, please provide those documents with the changes easily identifiable (i.e., highlight changes, etc.).

The OPTN bylaws and policies guide the sequence of allocation and wait listing practices of OPTN members in an effort to assure equitable organ allocation for transplant. The bylaws and policies also guide safe and effective practice connected to organ transplantation and living donor care. UNOS is responsible for [redacted] compliance by OPTN members with these OPTN obligations, as well as for processing reports of transplant-related patient safety and living donor safety.

The OPTN MPSC, and in certain cases, the OPTN Board of Directors, perform the peer review functions of the OPTN. Please be aware that this correspondence and all documents and information requested by UNOS staff, on behalf of the OPTN, are protected by applicable peer review statutes and will not be

disclosed. For this reason, all associated reports, inquiries, deliberations, findings, recommendations, and actions must be kept confidential. This means we will not be able to provide you with the results of our investigation.

I look forward to hearing from you by **January 14, 2021**. Responses can be sent via mail, email and/or fax. I can be contacted at [redacted]. Thank you in advance for providing the additional information requested.

Sincerely,

[redacted]
Safety Analyst
UNOS Member Quality

cc: [redacted] OPTN Alternate Representative
[redacted] Director, UNOS Member Quality

[redacted]

From: [redacted]@dnwest.org>
Sent: Thursday, January 14, 2021 4:28 PM
To: [redacted]
Cc: [redacted]; [redacted]
Subject: [EXTERNAL] UNOS Request for Information - CADN - Donor [redacted]
Attachments: [redacted] ABO Mismatch Response Binder.pdf

Dear [redacted],

Attached is our response to your request for information related to Donor [redacted]

Thank you,

[redacted]

[redacted]

DonorNetworkWest.org

DONOR NETWORK WEST

1/14/2021

[redacted]
Safety Analyst
UNOS Member Quality
United Network for Organ Sharing
[redacted]

[redacted]

Regarding: Confidential Medical Peer Review of [redacted]- ABO Mismatch

Dear [redacted]:
We are providing additional information to facilitate the UNOS medical peer review of our incident involving the listing of donor [redacted] as blood type O, when the donor was actually blood type B.
The information you requested is in blue, followed by our response.

Provide a detailed timeline and review of the ABO determination for this donor including:

- The draw date/time and result date/time of every sample sent for or used to determine donor ABO (including cancelled tests, invalid results, etc.);

  See attachment 1. ABO Testing Timeline

- Documentation for each of these blood draws and results, including the result(s) that found the presence of ABO B in donor serum;

  See attachment 2. ABO Results

- Complete transfusion records and hemodilution calculations;

  See attachment 3. Transfusion and Hemodilution

- A detailed summary of all discussions related to the donor's ABO results and concerns for validity of the results. Include when these discussions occurred and a detailed list of the individuals who participated;

  See Attachment 4. Discussions Related to ABO Results

- A description of all factors considered when CADN decided to allocate organs as ABO O.

  See Attachment 5. Factors Considered When Allocating as ABO O

Provide a root cause analysis, or post-case review, of the ABO determination and reporting.

See Attachment 6. Post-Case Review

Provide a detailed timeline and review of the communication with evaluating and accepting centers, including:

- What centers were told regarding the donor's ABO before procurement, especially in regards to the mixed O and B results

  Beginning prior to generating UNOS match runs, CAIM was contacted on 12-21-2020 to evaluate a directed donation request, which included verbal discussion about having two hospital ABO results as O Positive. CAIM was updated later that day that allocation was on hold due to CADN's need to clarify ABO status and consult UNOS.

  Following the recommendations provided by UNOS during a consultation call with CADN Clinical Procurement Coordinator (CPC) on 12-21-2020, CADN placed the following information into DonorNet's Donor Highlights:

  > "Pt is s/p MTP (see blood products page for quantity) with ABO resulting O+ after x2 type and screens drawn at the donor hospital. No ABO or blood samples were drawn on initial admission to hospital prior to MTP being initiated. Hospital ABO continues to result inconclusive. ID samples did not result an ABO. Per hospital trauma blood bank, when typing the pt, the red cells type as O however the serum types as B. The staff has to add more serum in order for the sample to result; the result is O+."

  Transplant centers receiving provisional offers down the thoracic and abdominal match runs were informed about the donor's ABO testing following the patient's massive transfusions at the originating hospital, the ABO testing at Community Regional Medical Center, and non-resulted testing from CADN's ABO/infectious disease testing lab as outlined in DonorNet Donor Highlights.

  See attachment 4. Discussions Related to ABO Results.
  See attachment 7. Communication with Evaluating and Accepting Centers.

- Concerns communicated to CADN by evaluating or accepting centers regarding the validity of the reported ABO,

  On 12-22-2020, after considering a directed donation kidney offer for greater than 24 hours, CAIM declined the offered kidney reporting "too much concern" amongst their program and HLA directors to accept the offer. CAIM expressed concern for potential ABO incompatibility after the donor had received blood products.

  Provisional offers down the kidney match run yielded concern from CAPC after ABO testing performed was reviewed with the CADN Clinical Operations Manager (COM). The reason for decline discussed was "it seems unclear what the blood type actually is." CAPC did not want to put their potential transplant recipients (PTR) at risk because of ABO discrepancy.

  As CADN continued offers for the kidney and pancreas, CASF expressed concerns questioning why other centers were declining this young donor's organs. [redacted] [redacted] (CASF) initiated a direct consultation between the CASF and donor hospital blood banks to review and clarify donor's ABO. Following consult, CASF accepted kidney offer and expressed no remaining concerns. They believed that the donor was accurately typed.

  The accepting center for the donor liver, CASU, expressed ABO incompatibility was of no concern.

  Although CASU heart program shared no initial concerns and accepted the primary heart offer on 12-22-2020 at 14:52 PST, the CASU heart team expressed apprehension two hours prior to the scheduled organ recovery time while patient was en route to recovery facility. This concluded with a request by CASU to delay the recovery 48-72 hours to facilitate additional ABO testing. Due to CADN confidence in ABO testing resulting in O Positive, lack of available ICU space from COVID-19 virus cases, two accepting abdominal centers with blood bank expert consults, and the family concerns with overall case length, CADN decided not to accommodate the two-to-three-day delay for additional ABO testing requested by CASU and CASU declined the heart.

  Following the late decline by CASU prior to the scheduled recovery time, CAPM expressed concern. [redacted] (CAPM) requested additional information related to the testing of the ABO and consulted with [redacted] (CASF). Following the review of the consult performed between CASF and donor hospital blood banks with [redacted] (CASF), [redacted] CAPM) expressed his comfort with all information and accepted the kidney/pancreas for transplant.

  See attachment 4. Discussions Related to ABO Results.
  See attachment 7. Communication with Evaluating and Accepting Centers.

- When CADN first heard that there were recipient issues that suggested rejection, and when and how CADN communicated this information to other recipient centers;

  On 12-23-2020 at 10:06, CADN was updated by [redacted] (CASD) that the heart recipient was demonstrating rejection of the organ and the medical team was concerned for ABO incompatibility. CADN Organ Allocation Coordinator (OAC) immediately escalated this to the Manager of Allocation and Clinical Operations Manager and requested that other transplant centers (CAPM, CASF, and CASU) be notified of ABO incompatibility concern and to check status of transplant recipients.

  CADN OAC called CASU and was updated that the liver can tolerate ABO incompatibility and the recipient was doing well.

  CADN OAC called CAPM to speak to [redacted] who was in the OR. Notified the CAPM OR circulator, [redacted] of the current situation and that CASD was suspecting ABO incompatibility. [redacted] inquired how the liver recipient was doing and this was reported that at the time the liver recipient was doing fine. After internal discussion in the operating room, OR circulator, [redacted] reported the team decided to proceed and will be completing the transplant.

  CADN OAC contacted [redacted] (CASF) who stated the recipient of the right kidney was "doing fine." All calls to receiving transplant centers completed by 12:36 on 12-23-2020.

  See attachment 4. Discussions Related to ABO Results.
  See attachment 7. Communication with Evaluating and Accepting Centers.

- When CADN first heard that a confirmed ABO B result was discovered;

  Documentation of confirmed ABO result of B Positive was received from CADN ABO/Infectious Disease testing lab VRL/Eurofins on 12-23-2020 at 16:35. This result was from blood drawn at the start of donor work up on 12-20-2020 at 11:45. In addition, on 12-23-2020 at 17:39, CAPM reported verbally that blood testing on specimen provided with SPK tested weakly ABO B. Documentation of confirmed ABO result of B positive from CAPM was received on 12-24-2020 at 11:50

  See attachment 4. Discussions Related to ABO Results.

- What communication CADN had with centers after the ABO B result was discovered

  ABO result of B Positive was reported on 12-23-2020 at 16:35 was communicated to all receiving transplant centers by CADN clinical operations staff.

  - 12-23-2020 at 17:53 - CADN Clinical Operations Manager updated [redacted] (CAPM) of result.
  - 12-23-2020 at 17:59 - CADN Clinical Operations Manager updated [redacted] (CASD) of result.
  - 12-23-2020 at 18:01 - CADN Vice President of Strategic Partnerships updated [redacted] (CASF) of result.
  - 12-23-2020 at 18:20 - CADN Clinical Operations Manager updated [redacted] (CASU) of result.

  See attachment 4. Discussions Related to ABO Results.
  See attachment 7. Communication with Evaluating and Accepting Centers.

Provide your Standard Operating Procedures and/or policies for donor ABO determination and reporting, and process for addressing conflicting or indeterminate primary blood type results.

See Attachment 8. SE-M-001 Infectious Disease and ABO Testing Manual

Provide any quality assurance measures, and/or tools or resources used to determine and report donor ABO, particularly any relevant to situations when the donor's blood is drawn post-transfusion, if applicable.

CADN has a procedure and guidelines included in Attachment 8 that describe a process for verifying ABO and addressing discrepant results. However, our procedure did not define how to address invalid or cancelled tests. The two final source documents verifying the ABO as O Positive were not recognized as discrepant. Our updated policy addresses these issues.

What corrective actions have been implemented or are planned as a result of this event? If corrective actions include revisions to existing documents, please provide those documents with the changes easily identifiable (i.e. highlight changes, etc.).

ACTIONS IMPLEMENTED OR PLANNED AS A RESULT OF THIS EVENT:

- Immediate Corrective Action Communications.
  - See Attachment 9. Short Term Prevention.

- Revise ABO Testing and Verification policy (February 15th effective date)
  - See Attachment 10. DRAFT ABO Testing and Verification Policy with changes.

- Revise ABO / Subgroup Verification Training Curriculum (February 15th effective date)
  - CADN is revising ABO and Subgroup Testing and Verification training curriculum to include the content of the new procedure and competency assessment on an ongoing basis and no less than annually.

- Establish a formal process for direct notification of cancelled results to CADN from its contracted testing lab (VRL/Eurofins).

- Establish a HARD STOP procedure to describe steps taken when patient safety issues are recognized (DRAFT in progress. February 15th effective date).

Sincerely,

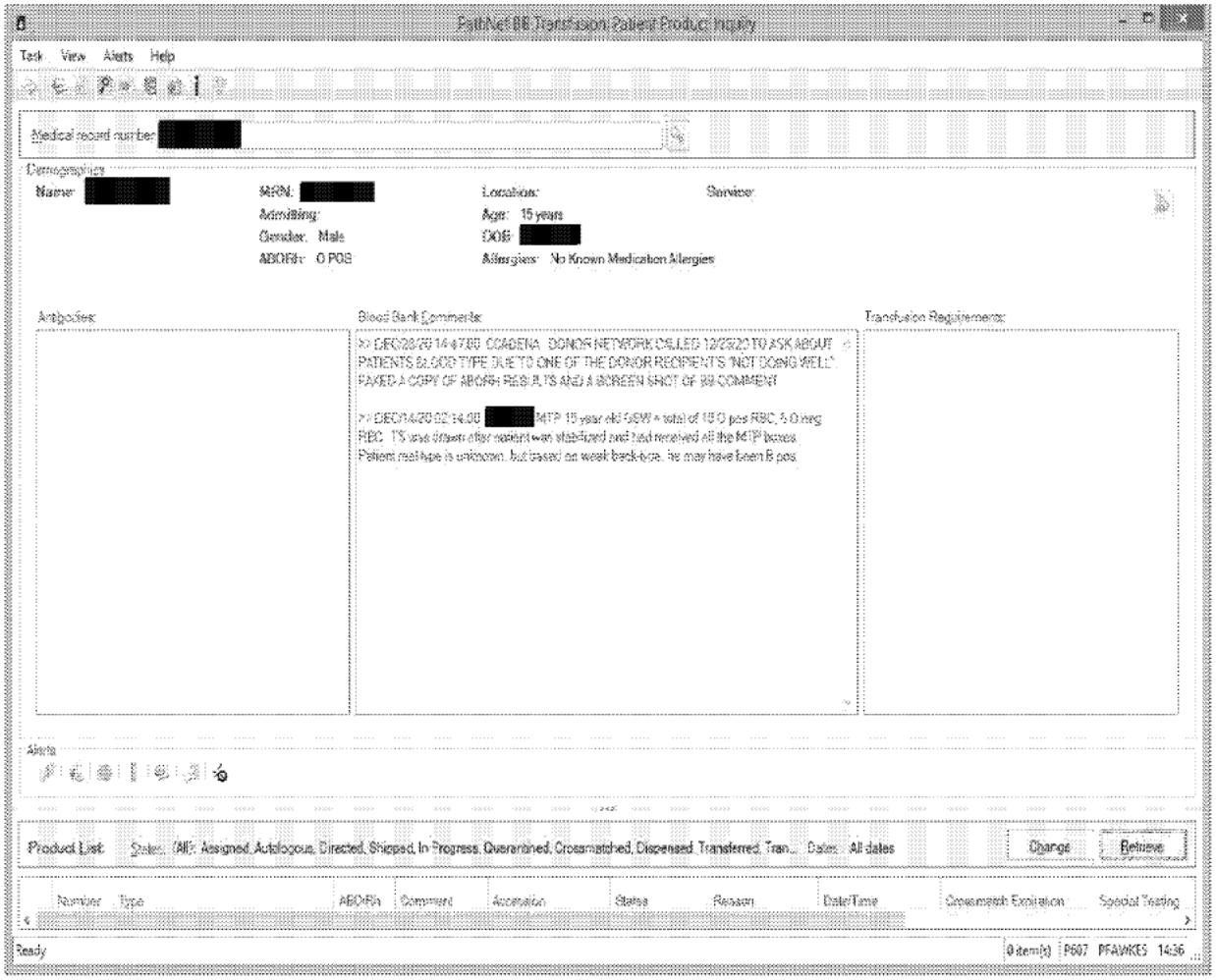
[redacted] [redacted]

Attachment 1. [redacted] ABO Testing Timeline

	Lab	Draw Date / Time	Result Date / Time	Result	LAB COMMENTS – On test results	DNWEST COMMENT
1	Kaweah Delta Medical Ct.	12-13-2020 @ 2315	12-14-2020 0209	O Positive	BLOOD BANK COMMENT - Lab Notes: >> DEC/14/20 02:14:00 [redacted] MTP 15 year old GSW = total of 16 O Positive RBC, 6 O neg RBC. TS was drawn after patient was stabilized and had received all the MTP boxes. Patient real type is unknown, but based of weak back-type, he may have been B Pos.	We obtained verbal results on 12-15-2020. Hard copy was obtained after cross clamp.
2	CRMC Hospital	12-14-2020 @ 0647	12-14-2020 @ 08:40	O Positive	Corrected Results: Previously reported as: INVLD on 12-14-2020 at 07:41	
3	CRMC Hospital	12-20-2020 @ 11:45	12-20-2020 @ 14:33	O Positive	Corrected Results: Previously reported as: INVLD on 12-20-2020 at 12:56	
4	VRL / Eurofins San Ramon	12-20-2020 @ 11:45	12-20-2020 @ 23:01	Cancelled	Note: Unable to obtain valid result	
5	VRL / Eurofins Denver	12-20-2020 @ 11:45	12-23-2020 @ 16:32	B Positive		
6	CPMC	12-23-2020 @ 1350	12-24-2020 @ 11:18	B Positive		

Attachment 2. ABO RESULTS

Sample 1


PathNet BB Transfusion Patient Product Inquiry
Task View Alerts Help
Medical record number:
Demographics
Name:
MRN:
Admitting:
Gender: Male
ABO/Rh: O POS
Location:
Age: 15 years
DOB:
Allergies: No Known Medication Allergies
Service:
Antibodies:
Blood Bank Comments:
Transfusion Requirements:
Alerts
Product List
Status: All; Assigned, Autologous, Directed, Shipped, In Progress, Quarantined, Crossmatched, Dispensed, Transferred, Tran... Dates: All dates
Change
Retrieve
Number
Type
ABO/Rh
Comment
Accession
Status
Reason
Date/Time
Crossmatch Expiration
Special Testing
Ready
0 item(s)
PROD
PFAWKES
14:36

Sample 2

[redacted])

RH

Type and Screen

Collected: 12/14/20 0647
Result status: Final
Resulting lab: COMMUNITY REGIONAL MEDICAL CENTER LAB
Value: POS
*Additional information available - narrative

Type and Screen

Results

Status: Edited Result - FINAL (Collected: 12/14/2020 06:47)

Type and Screen

Order: [redacted]

Status: Edited Result - FINAL Visible to patient: No (not released) Next appt: None

Component	7 d ago
ABO Group	O

Comment: Corrected Results: Previously reported as: INVLD on 12/14/20 at 07:41 by [redacted]

RH	POS
Antibody Screen	NEG
Resulting Agency	CRMC

Narrative

Performed by: SOFTLAB

Quantity (Units)->2
Quantity (units)->1

Specimen Collected: 12/14/20 06:47 Last Resulted: 12/14/20 08:40

Order Details | View Encounter | Lab and Collection Details | Routing | Result History

vC=Value has a corrected status

Result History

Type and Screen on 12/14/2020

Encounter

View Encounter

Specimen ID	Bill Type	Client ID
[redacted]		

Additional Information

Specimen Date Taken	Specimen Time Taken	Specimen Received Date	Specimen Received Time	Result Date	Result Time
Dec 14, 2020	0647	Dec 14, 2020	0650	Dec 14, 20[redacted]	[redacted]

[redacted]) Printed by [redacted] RN [311146] a

Sample 3

[redacted]

ABO Group

Type & Screen

Collected: 12/20/20 1145
Result status: Corrected
Resulting lab: COMMUNITY REGIONAL MEDICAL CENTER LAB
Value: O
Comment: Corrected Results: Previously reported as: INVLD on 12/20/20 at 12:56 by yvilla
*Additional information available - comment

Type & Screen

Results

Status: Edited Result - FINAL (Collected: 12/20/2020 11:45)

Type & Screen

Order: [redacted]

Status: Edited Result - FINAL Visible to patient: No (not released) Next appt: None

Component	11:45
ABO Group	O VC
Comment: Corrected Results: Previously reported as: INVLD on 12/20/20 at 12:56 by [redacted]	
RH	POS
Antibody Screen	NEG
Resulting Agency	CRMC

Specimen Collected: 12/20/20 11:45 Last Resulted: 12/20/20 14:33

Order Details | View Encounter | Lab and Collection Details | Routing | Result History

VC=Value has a corrected status

Result History

Type & Screen on 12/20/2020

Encounter

View Encounter

Specimen ID	Bill Type	Client ID
[redacted]		

Additional Information

Specimen Date Taken	Specimen Time Taken	Specimen Received Date	Specimen Received Time	Result Date	Result Time
Dec 20, 2020	1145	Dec 20, 2020	1205	Dec 20, 2020	1433

Order Report

Sample 4

VRL | Eurofins Pre-Transplant Testing

Final Report

Order Details		Ordering Professional	Request / Accession	[redacted]
DNW Referral ID	[redacted]	2341 - Donor Network West - OPO	Received	12/20/2020 18:10
UNOS#	[redacted]	[redacted]	Final Report	12/20/2020 23:01
Name	[redacted]		Report Generated	12/20/2020 23:01
DOB	[redacted]		Time Zone	Pacific Standard Time
Gender	M			

Flagged Results

Test	Completed	Results	Ref. Range
CMV IgG (EIA)	12/20/2020 21:41	**Equivocal**	Negative
EBV IgG (EIA)	12/20/2020 21:53	**Positive**	Negative

Results

Test	Completed	Results	Ref. Range
ABO/Rh - Micro Typing System	12/20/2020 22:21	**Cancelled**	
Unable to obtain a valid result.			
Cocci IgG (EIA)	12/20/2020 22:17	**Negative**	Negative
Cocci IgM (EIA)	12/20/2020 22:19	**Negative**	Negative
Hepatitis B Core Total Ab	12/20/2020 22:14	**Non Reactive**	Non Reactive
Hepatitis B Surface Ag	12/20/2020 22:12	**Non Reactive**	Non Reactive
Hepatitis C Virus Ab	12/20/2020 22:16	**Non Reactive**	Non Reactive
HIV-1/HIV-2 Plus O	12/20/2020 21:39	**Non Reactive**	Non Reactive
Syphilis Screening - Nontreponemal	12/20/2020 20:39	**Non Reactive**	Non Reactive
Toxoplasma IgG (EIA)	12/20/2020 21:56	**Negative**	Negative
Ultrio Elite HBV	12/20/2020 22:59	**Non Reactive**	Non Reactive
Ultrio Elite HCV	12/20/2020 22:59	**Non Reactive**	Non Reactive
Ultrio Elite HIV-1/2	12/20/2020 22:59	**Non Reactive**	Non Reactive
WNV	12/20/2020 23:01	**Non Reactive**	Non Reactive
WNV IgM	12/20/2020 22:47	**Negative**	Negative

Order Details		Ordering Professional	Request / Accession	[redacted]
DNW Referral ID	[redacted]	2341 - Donor Network West - OPO	Received	12/20/2020 18:10
UNOS#	[redacted]	[redacted]	Final Report	12/20/2020 23:01
Name	[redacted]		Report Generated	12/20/2020 23:01
DOB	[redacted]		Time Zone	Pacific Standard Time
Gender	M			

Additional Results

Test	Completed
nPOD	12/20/2020 22:15

GADA	Negative
IA2	Negative

Sample Reference(s)

Collection Time Zone: Pacific Standard Time

VRL Sample ID	Type	Collected	Test(s)
[redacted]	Serum - Red Top	12/20/2020 11:45	109, 2735, 2736, 3124, 3211, 3214, 3221, 3513, 3521, 3535, 3545, 3551
Donor Type: *Pre-Mortem* ***Transfusion:*** *Post-Transfusion*			
[redacted]	Plasma - EDTA	12/20/2020 11:45	1400, 2722, 2771, 2772, 2773
Donor Type: *Pre-Mortem* ***Transfusion:*** *Post-Transfusion*			
[redacted]	Plasma - EDTA	12/20/2020 11:45	
Donor Type: *Pre-Mortem* ***Transfusion:*** *Post-Transfusion*			
[redacted]	Serum - Red Top	12/20/2020 11:45	
Donor Type: *Pre-Mortem* ***Transfusion:*** *Post-Transfusion*			

Test Reference(s)

Code	Name	Methodology Description
1400	ABO/Rh - Micro Typing System	ABO typing performed using Ortho Gel Cards and reagents.
3124	CMV IgG (EIA)	BioRad CMV IgG Ab (EIA) Test.
2735	Cocci IgG (EIA)	Omega Coccidioides IgG Ab (EIA) Test.
2736	Cocci IgM (EIA)	Omega Coccidioides IgM Ab (EIA) Test.
3513	EBV IgG (EIA)	BioRad EBV IgG Ab (EIA) Test.
3211	Hepatitis B Core Total Ab	Ortho HBc ELISA is a qualitative ELISA for the detection of total antibody.
3214	Hepatitis B Surface Ag	BioRad Genetic Systems HBsAg EIA 3.0 is FDA approved for living and cadaveric donor screening.
3221	Hepatitis C Virus Ab	ORTHO HCV Version 3.0 ELISA is FDA approved for living and cadaveric donor screening.
3521	HIV-1/HIV-2 Plus O	BioRad GS HIV-1/HIV-2 Plus O EIA is FDA approved for living and cadaveric donor screening. This is a screening assay; it is neither a diagnostic assay nor a confirmatory test for the presence of HIV.

Order Details		Ordering Professional	Request / Accession	
DNW Referral ID	[redacted]	2341 - Donor Network West - OPO	Received	12/20/2020 18:10
UNOS#	[redacted]	[redacted]	Final Report	12/20/2020 23:01
Name	[redacted]		Report Generated	12/20/2020 23:01
DOB	[redacted]		Time Zone	Pacific Standard Time
Gender	M			

3545	nPOD	Kronus ELISA for the determination of glutamic acid decarboxylase antibody (GAD) and IA-2 antibody in human serum.
3551	Syphilis Screening - Nontreponemal	ASiManager-AT RPR Card Test for Syphilis. FDA-licensed test for cadaveric and living-donor screening.
3535	Toxoplasma IgG (EIA)	Qualitative detection of anti-Toxoplasma gondii IgG in human serum by EIA; not approved by the FDA for donor screening.
2773	Ultrio Elite HBV	The Procleix Ultrio Elite Assay is FDA licensed for living and cadaveric donor screening by TMA for the detection of HBV.
2772	Ultrio Elite HCV	The Procleix Ultrio Elite Assay is FDA licensed for living and cadaveric donor screening by TMA for the detection of HCV.
2771	Ultrio Elite HIV-1/2	The Procleix Ultrio Elite Assay is FDA licensed for living and cadaveric donor screening by TMA for the detection of HIV-1 and HIV-2.
2722	WNV	The Procleix WNV assay is a qualitative in vitro nucleic acid system for the detection of WNV RNA in plasma and serum specimen. This is a screening assay and is not intended for use as an aid in the diagnosis of WNV. This assay is FDA licensed for both living and cadaveric donor screening.
109	WNV IgM	Test performed by using the FOCUS DxSelect ELISA assay.

Sample 5

VRL | Eurofins Pre-Transplant Testing

Final Report

Order Details		Ordering Professional	Request / Accession	[redacted]
DNW Referral ID	[redacted]	2341 - Donor Network West - OPO	Received	12/20/2020 18:10
UNOS#	[redacted]	[redacted]	Final Report	12/23/2020 16:32
Name	[redacted]		Report Generated	12/23/2020 16:32
DOB	[redacted]		Time Zone	Pacific Standard Time
Gender	M			

Results

Test	Completed	Results	Ref. Range
ABO/Rh	12/23/2020 16:32	**B Positive**	

Sample Reference(s)

Collection Time Zone: Pacific Standard Time

VRL Sample ID	Type	Collected	Test(s)
[redacted]	Plasma - EDTA	12/20/2020 11:45	1405

Donor Type: *Pre-Mortem* ***Transfusion:*** *Post-Transfusion*

Test Reference(s)

Code	Name	Methodology Description
1405	ABO/Rh	ABO typing performed using BioRad reagents.

Laboratory: *VRL Eurofins*
[redacted]
CLIA #: [redacted]
Laboratory Director: [redacted]

Sample 6

Print Date/Time: 12/24/2020 11:22 INTERIM REPORT

California Pacific Medical Center

[redacted] MD, Medical Director

MR #: [redacted] Acct: [redacted] Name: [redacted]1,DONOR ID
DOB : [redacted] 15Y/U
Loc : VCLABA
Admit Date: 12/24/2020

[redacted] COLL: 12/23/2020 13:50 REC: 12/24/2020 11:18 PHYS: [redacted]

ABORH Patient

ABORH	B Positive	{VN}
BB Comment Charted:	MIXED FIELD REACTION WITH ANTI B, CONSISTENT WITH RECENT TRANSFUSION OF O CELLS	{VN}

{VN} = Performed at: CPMC Van Ness Campus, 11[redacted]

Attachment 3. Transfusion and Hemodilution

[redacted] 12/23/2020 03:24 Pacific - XClamp

CASE ID: [redacted] UNOS: [redacted] TISSUE ID: [redacted]

O	M SEX	15 YEARS	H RACE	[redacted] DOB	178 CM	90.4 KILOGRAMS	NO REGISTERED

BLOOD PRODUCT/COLLOID ADMINISTRATION SUMMARY

☐ Not Given

Date-Time Completed	Blood Colloid Type	Other Type	Volume mL
12/13/2020 - 20:53	Blood Product - RBC		250
12/13/2020 - 20:53	Blood Product - RBC		250
12/13/2020 - 21:11	Blood Product - RBC		250
12/13/2020 - 21:11	Blood Product - RBC		250
12/13/2020 - 21:11	Blood Product - RBC		250
12/13/2020 - 21:11	Blood Product - RBC		250
12/13/2020 - 21:11	Colloid - FFP/Plasma		215
12/13/2020 - 21:11	Colloid - FFP/Plasma		218
12/13/2020 - 21:11	Colloid - FFP/Plasma		246
12/13/2020 - 21:11	Colloid - FFP/Plasma		214
12/13/2020 - 21:11	Colloid - Platelets		223
12/13/2020 - 21:27	Blood Product - RBC		300
12/13/2020 - 21:27	Blood Product - RBC		300
12/13/2020 - 21:27	Blood Product - RBC		300
12/13/2020 - 21:27	Blood Product - RBC		300
12/13/2020 - 21:44	Blood Product - RBC		300
12/13/2020 - 21:44	Blood Product - RBC		300
12/13/2020 - 21:44	Blood Product - RBC		300
12/13/2020 - 21:44	Blood Product - RBC		300
12/13/2020 - 21:44	Colloid - FFP/Plasma		205
12/13/2020 - 21:44	Colloid - FFP/Plasma		322
12/13/2020 - 21:44	Colloid - FFP/Plasma		209
12/13/2020 - 21:44	Colloid - FFP/Plasma		206
12/13/2020 - 21:44	Colloid - Platelets		286
12/13/2020 - 21:58	Blood Product - RBC		300
12/13/2020 - 21:58	Blood Product - RBC		300

Highlighted units of Colloid (this and subsequent page) are the same unit. They were listed x2 by the hospital and recorded as such in our electronic donor record. The error was identified by DNWest upon retrospective review. No impact on sample qualification for ID testing.

Date-Time Completed	Blood Colloid Type	Other Type	Volume mL
12/13/2020 - 21:58	Blood Product - RBC		300
12/13/2020 - 21:58	Blood Product - RBC		300
12/13/2020 - 21:58	Colloid - FFP/Plasma		208
12/13/2020 - 21:58	Colloid - FFP/Plasma		209
12/13/2020 - 21:58	Colloid - FFP/Plasma		209
12/13/2020 - 21:58	Colloid - FFP/Plasma		210
12/13/2020 - 21:58	Colloid - Platelets		321
12/13/2020 - 22:17	Blood Product - RBC		300
12/13/2020 - 22:17	Blood Product - RBC		300
12/13/2020 - 22:17	Blood Product - RBC		300
12/13/2020 - 22:17	Blood Product - RBC		300
12/13/2020 - 22:17	Colloid - Platelets		304
12/14/2020 - 08:42	Colloid - FFP/Plasma		250
12/14/2020 - 08:53	Colloid - Cryoprecipitate		100
12/14/2020 - 09:05	Colloid - Cryoprecipitate		100
12/14/2020 - 09:31	Colloid - FFP/Plasma		250
12/21/2020 - 03:08	Colloid - Albumin 25%		100
mm/dd/yyyy - hh:mm	------		
mm/dd/yyyy - hh:mm	------		
mm/dd/yyyy - hh:mm	------		
mm/dd/yyyy - hh:mm	------		
mm/dd/yyyy - hh:mm	------		

Comments:
18 UNITS OF PRBC AND 4 UNITS OF WHOLE BLOOD, 12 UNITS OF PLASMA, 4 UNITS OF PLATELETS GIVEN AT KDH. All blood given with the date mark of 12/13 are from KDH and the time given is unknown, however the time documented is the time blood was checked out and was given as MTP.

[redacted] 12/23/2020 03:24 Pacific - XClamp

[redacted] CASE ID: [redacted] UNOS: [redacted] TISSUE ID: [redacted]

O

M	15	H	[redacted]	178	90.4	NO
SEX	YEARS	RACE	DOB	CM	KILOGRAMS	REGISTERED

TRANSFUSION/INFUSION - HEMODILUTION WORKSHEET

<< Hemodilution 1 of 1 >>

Note - Patient's Weight and Date-Time Sample Drawn must already be entered for calculations to work properly

Existing Draw Date-Time: ------ **Pacific**

Date-Time sample drawn: **12/20/2020** - **11:45** **PST** ○ Pre-Transfusion ◉ Post-Transfusion

Transfusion of blood products within 48 hrs prior to specimen draw or asystole

Date-Time	Blood Type	Volume
No records found.		

Infusion of colloids within 48 hrs prior to specimen draw or asystole

Date-Time	Colloid Type	Volume
No records found.		

Weight: 90.4 kilograms (199.3 pounds)

ESTIMATED TOTAL PLASMA VOLUME (TPV)

TPV = Donor Wt (kg) 90.4 / 0.025

TPV = 3616.00 mls

ESTIMATED TOTAL BLOOD VOLUME (TBV)

TBV = Donor Wt (kg) 90.4 / 0.015

TBV = 6026.67 mls

A: TOTAL VOLUME OF BLOOD TRANSFUSED IN THE LAST 48 HOURS

RBC's (packed cells)	=	--	mls
Whole Blood	=	--	mls
Other Blood Products	=	--	mls
Total of A	=	0.0	mls

B: TOTAL VOLUME OF COLLOIDS INFUSED IN THE LAST 48 HOURS

FFP/Plasma	=	--	mls
Platelets	=	--	mls
Cryoprecipitate	=	--	mls
Albumin 5%	=	--	mls
Albumin 25%	=	--	mls
Dextran	=	--	mls
Other Colloids	=	--	mls
Total of B	=	0.0	mls

C: TOTAL VOLUME OF CRYSTALLOIDS INFUSED IN LAST HOUR

Date-Time	Type	Other Type	Volume	
12/20/2020 - **10:45**	**Other**	**D5 .45NS**	**75**	mls
mm/dd/yyyy - hh:mm	------			mls

mm/dd/yyyy - hh:mm	------			mls
mm/dd/yyyy - hh:mm	------			mls

Total of C = 75.0 mls

D: DETERMINATION OF ELIGIBILITY

1) Is B + C < TPV?	(	0.0	+	75.0	=	75.0	) <	3616.00	?	YES
2) Is A + B + C < TBV?	(	0.0	+	0.0	+	75.0	=	75.0	) <	6026.67	?	YES

SAMPLE QUALIFIES

Comments: ☐ N/A

Attachment 4. Discussions Related to ABO Results

Attachment 4 Discussions Related to ABO Results

ACRONYMS:	**CADN STAFF POSITIONS:**
ASC = Ambulatory Surgical Center CCT = Critical Care Transport CRMC = Community Regional Medical Center iTX = I Transplant MTP = Massive Transfusion Protocol SRRMC = San Ramon Regional Medical Center TAT = Turn-around-time	AOD = Administrator of the Day COM = Clinical Operations Manager CPC = Clinical Procurement Coordinator DPC = Donation Program Consultant FRC = Family Resource Coordinator HDC = Hospital Donation Coordinator OAC = Organ Allocation Coordinator OPC = Organ Perfusion Coordinator

Date/Time *(Pacific Time)*	**Who/Where**	**Discussion/Notes**
12-14-2020 06:47	Community Regional Medical Center (CRMC)	Hospital lab collected ABO and resulted at 0741 as O POSITIVE. NOTE "COMMENT: Corrected results: Previously reported as: INVLD on 12-14-2020 at 07:41."
12-15-2020 17:04	Kaweah Delta District Hospital (KDH)	Verbal report from KDH Transfusion Medicine ABO lab result reported as O POSITIVE. [sample drawn 12-13-2020 at 23:15 and resulted 12-14-2020 02:10]
12-15-2020 17:21	iTX Note: [redacted]	Called Kaweah Delta District Hospital (KDH) blood bank to confirm transfusion record and was informed pt did not have an ABO drawn prior to massive transfusion protocol (MTP) being initiated. Pt true ABO type is unknown at this time. [iTx note time is 17:21. Call was made prior to 17:04]
12-15-2020 17:23	iTX Note: [redacted]	Called KDH blood bank, no blood samples were drawn from pt prior to receiving MTP, therefore no admit blood is held.
12-15-2020 17:25	iTX Attachments: [redacted]	KDH Transfusion Record attached to iTX at 17:25 by [redacted] ABO for patient references O POSITIVE.
12-15-2020 18:01	iTX Blood Products: [redacted]	KDH transfusion record updated in iTX blood products page. Accounted for 18 units of PRBC and 4 units of whole blood, 12 units of plasma, 4 units of platelets.
12-17-2020 17:12	[redacted]	[redacted]HDC) messages[redacted] (CPC) stating that CRMC Physician Assistant [redacted] had approached CADN staff to be sure they were aware that this patient had received MTP at KDH and that blood typing was showing O but the PA had received report of potential B. A repeat ABO test has not been drawn since 12-14-2020. [redacted] (CPC) updated [redacted]CPC) by text message.
12-20-2020 11:45	iTX Notes: [redacted]	Infectious disease/ABO testing drawn and courier arranged for transport to VRL[redacted]. Hemodilution

Attachment 4 Discussions Related to ABO Results

		completed by [redacted] CPC) at 11:45 and sample was qualified.
12-20-2020 12:00 (approx.)	[redacted]	[redacted] CPC) initiated case start following BD declaration on 12/20, including ID/ABO blood sent to VRL and ABO ordered at hospital. Donor was known to have had massive transfusion on 12/13 and additional blood products on 12/14. [redacted] (COM) was in contact with [redacted] (CPC) throughout the day by both phone and text regarding case start plan, diagnostics, DRIFT potential, etc.
12-20-2020 12:56	Community Regional Medical Center (CRMC)	Hospital lab collected ABO and resulted at 12:56 as O POS. NOTE "COMMENT: Corrected results: Previously reported as: INVLD on 12-20-2020 at 12:56."
12-20-2020 18:51	[redacted]	[redacted] COM) call to [redacted] (AOD) to discuss CADN policy in relation to moving forward with two hospital ABO's drawn at different times. [redacted] (AOD) confirmed CADN policy. .
12-20-2020 19:13	[redacted]	Text message from [redacted] CPC) to [redacted] (COM) confirming CRMC ABO sent at 11:45 resulted at 12:56 as O POSITIVE.
12-20-2020 23:01	iTX Attachments: VRL Lab, San Ramon	FINAL Infectious disease and ABO results. ABO CANCELLED, unable to obtain a valid result.
12-21-2020 02:18	[redacted] Contact Call Recording	[redacted] (OAC) reviews report and calls VRL lab. [redacted] (VRL) explains the lab obtained a mixed field result. The sample is being sent to the Denver lab for confirmation. Turn-around-time (TAT) quoted to be 2-3 days.
12-21-2020 02:21	[redacted]	[redacted] (OAC) text messages [redacted] (CPC) and [redacted] (COM) to report VRL was unable to determine ABO. Blood sample drawn on 12-20-2020 at 11:45 is being sent to Denver lab with turn-around-time (TAT) of 2-3 days. [redacted] (CPC) reviewed current ABOs which all resulted as ABO = O, including one at Kaweah Delta on 12/13, and two at CRMC on 12/14 and 12/20. No additional ABOs requested, as all 3 results were consistent as O POSITIVE.
12-21-2020 04:03	[redacted]	ABO Verification #1 in DonorNet – O POSITIVE
12-21-2020 07:00	[redacted] to [redacted]	COM Report: [redacted] (COM) notified [redacted] (COM) of three current ABO documents, and explained that first two were around the time of massive transfusion on 12-13 and 12-14, and the third was approximately one week later on 12-20. [redacted] (COM) updated that VRL specimen was pending send-out to Denver lab.

Attachment 4 Discussions Related to ABO Results

12-21-2020 11:50	CADN Communication: [redacted]	• [redacted] (CPC) questioned plan for the ABO and [redacted] COM) asked why. • [redacted] CPC) indicated that because it was not resulted on the I.D. results that more work up was needed to make it official. • [redacted] (COM) indicated there were two hospital ABOs. • [redacted] (OAC) contacted VRL and was updated they were unable to determine ABO and it was being sent to Denver lab with 2-3 day TAT. Will need second hospital ABO. Might want to check both hospital ABOs and make sure they are valid. Keep seeing the word "invalid" on them and not sure how to read them. • [redacted] (CPC) indicated it is because his red cells are recognized as "O" but his serum has not made up its mind what it wants to be so it keeps reading invalid. They keep adding more serum and it results as O. • [redacted] (CPC) states the two hospital ABOs should already be uploaded. • [redacted] (OAC) states, "so we are good?" • [redacted] (CPC) states that [redacted] (FRC) asked the donor family about any record of ABO and family did not know.
12-21-2020 12:55	[redacted]	[redacted] (OAC) informed [redacted] (CAIM) of possible directed donation. CAIM to review potential recipient information for match.
12-21-2020 Approx. 13:00	[redacted]	[redacted] (CPC) and [redacted] (COM) communicated via text message and phone call. [redacted] (COM) instructed [redacted] (CPC) to again verify ABO with CRMC trauma blood bank and detail the method used to verify O POSITIVE. [redacted] (COM) requested that [redacted] (CPC) call UNOS with ABO information for consultation.
12-21-2020 16:50	iTX Note: [redacted]	Pre-Allocation Huddle: ABO/subtype verification: O POSITIVE, verified by JMB and LAY
12-21-2020 17:45	[redacted]	[redacted] (CAOP) call to CADN regarding directed donation offers to CAIM. [redacted] (OAC) updates that allocation is on hold because CADN needs to speak with UNOS. CADN

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		has multiple O Positive results, but donor could be B as updated by CRMC lab. CADN may need to re-draw tomorrow to verify and move forward.
12-21-2020 17:45	[redacted] United Network for Organ Sharing (UNOS) – CALL TRANSCRIPTION	[redacted] Organ Center, this is [redacted] • [redacted] Hi [redacted] my name is [redacted] [redacted] I work for Donor Network West in California. I have a question regarding, I guess, UNOS Policy (question mark). I really don't know how I am going to ask, but I am going to try. A patient we are currently working up for organ donation, this patient unfortunately came in, was admitted and had an emergent thoracotomy in the ED and was massively transfused. He received over 30 units of products. • [redacted] Oh wow. • [redacted] And so, this all happened on the day that he was admitted on 12/13 into the 14th. And so, unfortunately again, because everything was emergent, he never had an ABO, he never had a type and screen, he never had any of that done prior to being massively transfused. So, they did a type and screen after this and he came back as O POSITIVE. • [redacted] Right • [redacted] This is a 15-year-old male. And so, subsequently so, he received, the majority of his products were O POSITIVE. And so, we drew ID, all of that, two days ago so he is not hemodiluted, however, the ABOs that are coming back are still resulting as O POSITIVE but the issue is that when these ABOS are resulted, what happens is that when they go to type him, the red cells are identifying as O however the serum is identifying as B and it is throwing invalid for the ABO. So the techs have to add more serum to it. Once they add more serum then it results as O positive. And so, there on the ABO, the hospital ABO, it says FINAL and it says O Pos but there's also a note in there that says that it was "inconclusive" or something to those terms. And so my question is after all of that, at what point do we feel comfortable with an ABO from a hospital on a patient that has been transfused when we know that its whole circulatory blood products is not his and how do we get that out because we can… • [redacted] The samples are not considered hemodiluted?

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		• [redacted] That's correct. Because it has been past 48 hours since he received any products it's just the blood that's circulating within his body are not his red blood cells per se. • [redacted] Right • [redacted] And we sent out our infectious disease and HLA and the ABO that's supposed to result in the ID sample came back inconclusive. And so our infectious disease does not have an ABO. We are just going off of the two ABOs from the hospital. So when giving out offers, how do we navigate that in a way where we can say with confidence that that is his true ABO. Does that make sense? • [redacted] Yeah that's a little tricky, let's see… • [redacted] I know that we can send his blood out further past our capabilities and get it tested further, but it'll take two days and he is ready for allocation now and we're trying to set OR for tomorrow. But again, I don't want to start allocation with a question mark in the back of my mind about his true ABO. • [redacted] Right, ok, so if you take a look at, actually the policy that is going to cover this is 2.5 and 2.6. 2.5 and, basically 2.5 covers hemodilution assessment. So,what it states (reads policy 2.5). 2.6 covers a little bit more in depth what needs to be done to determine blood type so I'm guessing you have two samples drawn on two separate occasions, different collection times, submitted separately ([redacted] yes, uh huh). Ok, the best thing that I can tell you to do, because what it's also saying here is that documentation is needed to showing blood type determination is conducted according to your own written protocol, and a complete history of all blood products received by the donor since admission needs to be in the donor's medical record. So, as long as all of that is there, you should be okay; but because this is such a unique situation, I would definitely recommend putting something in donor highlights, big and bold, so that everybody sees it. I would, when you go notify primary centers that should be the first thing that you let them know. You know, just be very above board about everything. But as long as the documentation is there of received blood products and the two ABO source

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		documents and hemodilution worksheet and all that, as long as all that is in there, you should be okay. • [redacted] Okay. Alright then. Sounds like a plan. Have you had, I guess, any record on hand when somebody has been mass transfused and then later is a different ABO? In your experience? • [redacted] So, in my experience this is a fairly new situation for me, granted I've only been doing this for a couple of years. That being said, most of the time, it has been hemodiluted samples that I've seen come through. That being said I am sure that similar situations have occurred but just personally I haven't worked with any. • [redacted] Yeah, the only thing, I guess that is concerning of me is that the serum to me is coming back as B but the red cells are coming back as O. Which in my head makes sense, right, I mean you transfuse, all those red cells are there but the foundation is showing… that's why I am just like, ahh, it makes me nervous man. [redacted] Yeah, and again, all you can so is disclose everything. [redacted] Yeah…OK. Sounds like a plan. And, I am sorry, what is your name again? [redacted] My name is [redacted] [redacted] awesome. Well, thank you so much. Appreciate it. [redacted] Anytime. Is there anything else I can help you with, [redacted] [redacted] That's it sir. [redacted] Alright. Well you have a good rest of your evening. [redacted] Thanks. You too. Bye.
12-21-2020 19:03	CADN Communication: [redacted]	• [redacted] (CPC) reports that according to UNOS we are in policy. UNOS policy 2.5/2.6 addresses everything we have. The only thing we need to do is just make sure it is addressed in donor highlights and we tell that story to our centers. That is all he (UNOS) really had to say. I will make sure to write a note about it too. • [redacted] (CPC) responded to group that UNOS policy states that ok to proceed with information in donor highlights and to notify donor centers. [redacted] (CPC) had called CRMC trauma lab about invalid noted on ABO test. CRMC trauma lab stated that the

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		sample was read as O and serum as a B. Noted this as odd because they added serum which resulted as O.
12-21-2020 19:36	iTX Notes: [redacted]	"Called UNOS to verify pt ABO status. Pt is s/p MTP (see blood products page for quantity) with ABO resulting O POSITIVE after x2 type and screens drawn at the donor hospital. No ABO or blood samples were drawn on initial admission to hospital prior to MTP being initiated. Hospital ABO continues to result inconclusive. ID samples did not result an ABO. Per hospital trauma blood bank, when typing the pt, the red cells type as O however the serum types as B. The staff has to add more serum in order for the sample to result; The result is O+. After describing this to a UNOS representative, [redacted] he stated to follow policy 2.5/2.6. He recommended placing a note in the donor highlights in regarding the pt ABO as well as full disclosure to the transplant centers when offers are sent out."
12-21-2020 23:22	iTX Note: [redacted]	Entered "Pt is s/p MTP (see blood products page for quantity) with ABO resulting O+ after x2 type and screens drawn at the donor hospital. No ABO or blood samples were drawn on initial admission to hospital prior to MTP being initiated. Hospital ABO continues to result inconclusive. ID samples did not result an ABO. Per hospital trauma blood bank, when typing the pt, the red cells type as O however the serum types as B. The staff has to add more serum in order for the sample to result; The result is O+"
12-21-2020 23:37	DonorNet: Donor Highlights	Entered "Pt is s/p MTP (see blood products page for quantity) with ABO resulting O+ after x2 type and screens drawn at the donor hospital. No ABO or blood samples were drawn on initial admission to hospital prior to MTP being initiated. Hospital ABO continues to result inconclusive. ID samples did not result an ABO. Per hospital trauma blood bank, when typing the pt, the red cells type as O, however the serum types as B. The staff has to add more serum in order for the sample to result; The result is O+"
12-22-2020 07:00	[redacted]	Shift change report to [redacted] (COM). [redacted] COM) reviews transfusion history, CADN conversations with UNOS, and three O type ABO results and made [redacted] (COM) aware we were proceeding as ABO O and that [redacted] (AOD) was aware.
12-22-2020 15:41	iTX Notes: [redacted]	Call from CAIM regarding directed donation that after further discussion they believe this donor is too much of

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	Directed Donation	risk for ABO incompatibility and declined. Did not notify anyone because felt resolved.
12-22-2020 16:15	[redacted]	[redacted] provides backup liver offer to CASF stating they are behind national pediatrics and CASU but getting concerns since many are declining. When asked why she states that some are concerned for CIT, size and quality which confuses [redacted]
12-22-2020 17:00	[redacted]	OR Setting Huddle: Recovery location at San Ramon Regional Medical Center (SRRMC) Ambulatory Surgical Center (ASC) at 22:00 with recovery of heart, liver, pancreas and kidneys.
12-22-2020 17:04	[redacted]	Provides primary offer to [redacted] (CAPC) kidney program with discussion of ABO incompatibility concerns by CAIM. Coordinator states she will discuss with her surgeon.
12-22-2020 17:34	[redacted]	[redacted] (CAPC) surgeon calls in requesting further information. [redacted] (OAC) refers surgeon to [redacted] (COM) for ABO information and clarification outlined in DonorNet Donor Highlights and provides her direct phone number.
12-22-2020 17:54	[redacted]	Call from CAPC kidney coordinator declining for all patients due to the blood type discrepancy. States that their surgeon spoke with [redacted] (COM) and it seems unclear what the blood type actually is. CAPC does not want to put their potential transplant recipients (PTR) at risk because of ABO discrepancy.
12-22-2020 18:54	[redacted]	[redacted] (OAC) provides primary kidney offer to CASF/ [redacted] [redacted] (OAC) discussed ABO incompatibility concerns and why other programs have declined. He requests blood bank phone number so that he can have CASF blood bank call to verify all is safe. He also requests that [redacted] call UCSF Immunogenetics and Transplantation Laboratory (ITL) to verify Human Leukocyte Antigen (HLA) is ok as well.
12-22-2020 19:00	[redacted]	Verbal report from [redacted] (CPC) to [redacted] (CPC). Report includes discussion of ABO process and review of all documentation of testing. Also discussed the multiple huddles, communications and UNOS call resulting in listing patient as O Positive.
12-22-2020 19:05	[redacted]	Received phone call from CASU Thoracic surgeon, [redacted] He asked for clarification on Donor Highlight's statement regarding ABO verification to move forward with 22:00 OR. [redacted]) was just starting shift and

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		would follow up immediately with dayshift [redacted] (CPC).
12-22-2020 19:07	[redacted]	Called [redacted] (CPC) and received report. Informed [redacted] (CPC) of call received and [redacted] (CASU) concerns and potential to decline offer if not remedied. Made plan to have [redacted] (CPC) call [redacted] (CASU) and [redacted] (CPC) would alert [redacted] (COM) of the developing situation.
12-22-2020 19:15	[redacted]	[redacted] (COM) spoke with [redacted] (CASU) and answered questions about timing of transfusions, when ABOs were drawn, and results of ABOs [redacted] (CASU) reiterates he may decline and that he was going to reach out to the head of the UCSF blood bank, [redacted] for guidance and requested time to facilitate those conversations.
12-22-2020 19:18	[redacted]	Received call from [redacted] (CASU) Thoracic Coordinator. She apologized that she had not reached out prior to [redacted] (CASU). She wanted to understand what was happening and how allocation was able to proceed. I updated her with the information from UNET Donor Highlights page and let her know [redacted] (CPC) was reaching out to [redacted] (COM) while [redacted] (CPC) was calling [redacted] (CASU) back.
12-22-2020 19:22	[redacted] (CPC) [redacted] (COM)	[redacted] (CPC) called [redacted] (COM) with CASU Thoracic update. [redacted] (CPC) completed call with [redacted] (CASU) during this time and was added into the call. [redacted] informs team that CASU Thoracic requests a 2-3 day delay to complete additional ABO testing. Discussed options of patient return to CRMC or admit into SRRMC Intensive Care Unit. ASC delay would bump another CADN case scheduled donor transfer and recovery later in the morning of 12-23-2020. Due to the patient being in CCT to SRRMC ASC, a return to CRMC was not considered an option. Plan for [redacted] (COM) to contact CADN Administrator on Duty (AOD).
12-22-2020 19:29	CASF to CADN [redacted] (OAC) from Dr. John [redacted]	Updated that [redacted] (CASF) has consulted head of CASF Blood Bank, [redacted] who also called CRMC Blood Bank and all agree OK to proceed with donor as listed O Positive.
12-22-2020 19:34	[redacted] (AOD) [redacted] (COM)	[redacted] (COM) informed [redacted] (AOD) that CASU Thoracic concern and request for delay due to information provided in UNET Donor Highlights. CASU requested CADN hold organ recovery for two to three days to allow for additional ABO typing. AOD and COM agreed to ensure CASU was aware that donor was already in route to SRRMC ASC and that this information was posted in

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		DonorNet prior to offers as well as the call made to UNOS. Due to CADN confidence in ABO testing resulting in O Positive, lack of available ICU space from COVID-19 virus cases, two accepting abdominal centers with blood bank expert consults, and the family concerns with overall case length, CADN decided not to accommodate the two-to-three-day delay for additional ABO testing requested by CASU and CASU declined the heart.
12-22-2020 19:52	[redacted] (OAC) to CASF Dr. [redacted]	Clarifying call to [redacted] (CASF) to confirm that blood bank representative, [redacted] from CASF consulted CRMC blood bank and that the patient is correctly listed as O Positive.
12-22-2020 20:34	[redacted] (CPC)	[redacted] (CPC) received call from [redacted] (CASU) Thoracic Coordinator reporting that they are NOT coding out but will not be able to make the scheduled 22:00 incision time due to the need for ABO confirmation/verification.
12-22-2020 20:34	[redacted] (AOD) [redacted] (Donor Transfer Program Manager)	[redacted] (AOD) discussed possibility of ICU bed for the donor at SRRMC and requested call to SRRMC from [redacted] (Transfer Manager) who was informed that no ICU beds were available due to COVID.
12-22-2020 20:35	[redacted] (CPC)	[redacted] (CPC) updated by [redacted] (COM) of CADN trying to facilitate admission to SRRMC ICU to facilitate heart allocation. Updated [redacted] (COM) of last conversation with [redacted] (CASU) Thoracic Coordinator and their intent to delay OR.
12-22-2020 20:40	[redacted] (OPC) to [redacted] (COM) Statement	• [redacted] (OPC) informs [redacted] (COM) that CASD had been given an open offer and was interested in the heart. • [redacted] (COM) clarified that they made sure CASD understood why heart was declined and ensure all information was shared and reviewed. • CASD requests 20 minutes to review offer closely, donor records and all information in DonorNet. [redacted] (COM) communicated to [redacted] (AOD) and [redacted] (VP) to update and make sure they were aware and in agreement with open offer to CASD.
12-22-2020 20:46	[redacted] (COM) [redacted] (AOD)	[redacted] (COM) updated [redacted] (AOD) that heart was offered to CASD as open offer. [redacted] (AOD) reiterated to [redacted] (COM) to make sure that CASD knew of reason that CASU was declining heart. [redacted] (COM) acknowledged and stated she would ensure they received all information related to ABO.

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12-22-2020 20:54	iTX Note: [redacted] (OPC) Late entry 12-23-2020 16:18	Spoke with [redacted] (CASD) to see if they would have any interest in the heart. [redacted] A. (OPC) explained the donor was shot in the chest and had multiple transfusions. [redacted] stated he would review all information in DonorNet. [redacted] O. (OAC) granted CASD UNET access for review of chart prior to acceptance.
12-22-2020 21:41	[redacted] (OAC) to [redacted] (CASF)	[redacted] O. (OAC) call to [redacted] (CASF) to notify of OR time delay related to late heart decline r/t ABO incompatibility concern by CASU. Notifies that blood bank called second hospital, but patient received massive blood at KDH prior to being transferred. [redacted] (CASF) felt confident moving forward based on CASF blood bank consult with CRMC blood bank. [redacted] O. (OAC) asked [redacted] (CASF) if OAC could provide [redacted] (CASF) phone number should other centers want more information, to which he agreed.
12-22-2020 21:52	[redacted] (OAC) to [redacted] (CAPM)	Update call to [redacted] (CAPM) regarding decline of heart by CASU due to concern for ABO compatibility. [redacted] (CAPM) expresses concern stating he is leaning towards not accepting unless someone convinces him he does not have to worry about the blood type of the donor. He asks whether CASF obtained a blood bank consult and requests [redacted] (CASF) contact information.
12-22-2020 Immediately following	[redacted] (CAPM)	[redacted] (CAPM) contacts [redacted] (CASF) and is briefed on UCSF blood bank consult. [redacted] (CAPM) states he is comfortable moving forward.
12-23-2020 01:00	[redacted] (CPC)	CADN OR-F-025.02 *ABO Verification and OR Time Out Checklist* signed by [redacted] (CADN Qualified Healthcare Professional).
12-23-2020 02:00	[redacted] (CPC)	Verbal report to [redacted] (CADN), abdominal recovery surgeon including review of all source documents associated with ABO (CRMC ABO X 2 and VRL cancelled). CADN OR-F-025.02 *ABO Verification and OR Time Out Checklist* signed by [redacted] (CADN) 12-23-2020 at 02:00.
12-23-2020 02:23	[redacted] (CPC)	Verbal report to [redacted] (CASD), thoracic recovery surgeon, including review of all source documents associated with ABO (CRMC ABO X 2 and VRL cancelled). [redacted] (CASD) reported he was not aware of ABO situation and [redacted] (CPC) reviewed all documentation and UNET Donor Highlights with him. [redacted] (CASD) called accepting surgeon and confirmed accepting center had reviewed all ABO documents and cleared to proceed. CADN OR-F-025.02

Attachment 4 Discussions Related to ABO Results

		ABO Verification and OR Time Out Checklist signed by [redacted] (CASD) 12-23-2020 at 02:25.
12-23-2020 10:06	CASD Thoracic to [redacted] (OAC)	[redacted] (CASD) called [redacted] (OAC) to state that they were having trouble leaving the OR. Concerned that it may be ABO incompatibility, as the heart looked great upon arrival. [redacted] (OAC) stated that she had not heard of any concerns from other programs.
12-23-2020 Immediately following previous call	[redacted] (OAC) [redacted] (COM)	[redacted](OAC) initiates immediate escalation/notification to [redacted] (COM).
12-23-2020 Immediately following previous call	[redacted] (OAC) Valerie Chipman (Allocation Manager)	[redacted](OAC) notified [redacted]Allocation Manager) in CADN office to inform her and consult plan of action. Discussed with following plan: • [redacted] (OAC) would notify CASD that we would contact all other accepting centers to verify current patient status and notify them that the heart was not doing well with CASD's concerns for ABO incompatibility. • CADN would report to them (CASD) should any transplants appear to have any signs and symptoms of ABO incompatibility. Any further clinical questions regarding donor would be directed to the COM and if not available [redacted] (OAC) would provide contact to [redacted] (Allocation Manager).
12-23-2020 Immediately following previous call	[redacted] (OAC)	Call to Liver program (CASU). Relayed CASD patient status and their ABO incompatibility concerns, requested patient status and informed patient was doing well. [redacted] (OAC) was updated that the liver can tolerate ABO incompatibility.
12-23-2020 11:00 (approximate)	Valerie Chipman (Allocation Manager) [redacted] (OAC) [redacted] (COM)	[redacted] (OAC) received more communication from CASD requesting liver biopsy from CASU to evaluate function of transplanted organ. CASD expressed concern for ABO incompatibility. Updated [redacted] (COM) and [redacted] (Allocation Manager).
12-23-2020 11:32	[redacted] (COM) to [redacted] (AOD)	Incoming call from [redacted] (COM) stating update received from CADN allocation coordinator that CASD recipient was not doing well. Requested that [redacted] (COM) make calls to other centers and recipients were reported as "doing fine." CASD was investigating cause of failure.
12-23-2020 11:45	[redacted] (OAC)	[redacted] (OAC) called into the SPK OR to speak with Dr. Bry (CAPM) to check on the case. Notified CAPM OR

Attachment 4 Discussions Related to ABO Results

		circulator of CASD's current situation and belief that the patient is ABO incompatible. CAPM OR Circulator placed [redacted] (OAC) on speaker and [redacted] (OAC) relayed information to team. They were right at the point of anastomosis of the pancreas. [redacted] (OAC) was asked how the liver was doing and she stated they were doing well. The transplant team had a muffled discussion and decided to proceed.
12-23-2020 12:29	[redacted] (OAC)	Contacted [redacted] (CASF) and he updated that the kidney was working fine.
12-23-2020 12:36	[redacted] (OAC)	Called CAPM and told them that she had reached [redacted] (CASF) and the kidney was working fine.
12-23-2020 12:43	[redacted] (OAC)	A different person (unidentified) from CASD called requesting information and was provided [redacted] (COM) contact information.
12-23-2020 15:26	[redacted] (OAC)	Call from [redacted] (CAPM) that SPK failed and was removed, told that [redacted] (COM) would be notified.
12-23-2020 16:16	[redacted] (OAC)	[redacted] (OAC) call to CASU's liver attending surgeon to notify of SPK failure.
12-23-2020 16:35	iTX Attachments: VRL Lab, Denver	FINAL ABO result attached to iTX from ID/ABO blood draw 12-20-2020 11:45. ABO Result B Positive.
12-23-2020 17:39	[redacted] (OAC)	Call from [redacted] (CAPM) that UNOS [redacted] donor blood that came with SPK tested weakly ABO B at his center. Requested to speak to [redacted] (COM). Provided [redacted] (COM) contact information.
12-23-2020 18:40	[redacted] (COM) Summary of Events	• Notified by [redacted] (OAC) at 11:00 that heart recipient graft failing. • Notified by [redacted] (CASD) at 11:29 of heart recipient complications and being placed onto Extracorporeal Membrane Oxygenation (ECMO). • Request by [redacted] (CASD) at 16:00 with a request for a buccal swab from the donor for DNA ABO typing. Determined donor at [redacted] Coroner's Office. Discussed case with [redacted] (AOD) and will attempt to facilitate buccal swab. [redacted] (CASD) later called and requested no DNA swab rather attempts to speak with mom surrounding donor ABO, her or father's ABO. [redacted] (FRC) made a call to mother who was unable to answer questions surrounding ABO. • 17:53 - [redacted] (COM) updated [redacted] (CAPM) of result. • 17:59 - [redacted] (COM) updated [redacted] (CASD) of result. • 18:01 - [redacted] (VP Strategic Partnerships) updated [redacted] (CASF) of result.

Attachment 4 Discussions Related to ABO Results

		18:20 - [redacted] (COM) updated [redacted] (CASU) of result.
12-23-2020 12:47	[redacted] (OAC) to [redacted] at KDH blood bank	Asked if an admitting ABO was done. Requested a type and screen. Reports ABO as O POSITIVE. Asks if that was prior to transfusion. Reply is No. After stabilized and transfused. 16 O POS, and 6 O NEG RBCs. Real type is unknown but based on weak back type he may have been B POS and real type is unknown. It is not on the result but it is in a blood bank comment.
12-23-2020 14:05	[redacted] [redacted] (OAC) from KDH Blood Bank	Fax received from KDH showing ABO RH O POSITIVE and indistinguishable comment referencing possible B POS. Document attached to iTX at 14:09.
12-23-2020 16:35	iTX Attachments: VRL Lab, Denver	FINAL ABO result attached to iTX from ID/ABO blood draw 12-20-2020 11:45. ABO Result B POSITIVE.
12-24-2020 11:50	[redacted] (AOD) from Sutter Health CPMC	Fax received from [redacted], CAPM Transfusion Service per John L. (AOD) request on ABO result from blood sample sent with SPK. Resulted as B POSITIVE. COMMENT: Mixed field reaction with Anti-B, consistent with recent transfusion of O cells. Attached to DonorNet.

Attachment 5. Factors Considered When Allocating as ABO O

Attachment 5. Factors Considered When Allocating as ABO O

CADN allocated organs on UNOS ID# [redacted] as ABO O based on the multiple post-transfusion tests reporting the patient's blood group as O POS.

1. CADN performed the initial chart review on 12-15-2020, which included a review of all blood products received at Kaweah Delta District Hospital (KDH) and Community Regional Medical Center (CRMC).
2. A verbal report from Kaweah Delta District Hospital (KDH) to CADN from testing performed on a post transfusion sample drawn on 12-13-2020 at 2315 was reported as O POS.
3. An ABO test performed at Community Regional Medical Center (CRMC) on a post transfusion sample drawn on 12-14-2020 at 0647 was reported as O POS.
4. On donor initiation by CADN on **12-20-2020**, six days after patient blood transfusions, CADN obtained another sample for ABO testing and sent to CRMC at 1145 which was resulted as O POS.
    a. Both CRMC tests from 12-14-2020 and 12-20-2020 had a note "Corrected Results: Previously reported as: "INVLD" which was investigated by CADN onsite staff.
    b. CRMC blood bank verbally reported that patient's red blood cells were typing as O, however the serum types as a weak B. CRMC blood bank staff added additional serum to testing and the result was resulted as O.
5. Based on this information, CADN clinical coordinator consulted United Network for Organ Sharing (UNOS) for clarification on how to proceed. CADN was directed to follow OPTN policy 2.5 and 2.6 with additional recommendation to place ABO situation into DonorNet Highlights and fully disclose all information to transplant centers during allocation efforts through the match runs.
    a. All available ABO documents were reviewed, attached, and verified by CADN staff per DNWest policy SE-M-001.06 *Donor Network West Infectious Disease/ABO Testing Manual.*
6. The decision to list patient as O positive blood group was reinforced by discussion with CASF [redacted] who consulted UCSF blood bank and CRMC blood bank who confirmed O positive blood group for donor patient's specimens.

Attachment 6. Post Case Review

POST CASE REVIEW:

On 12-14-2020, CADN received an organ referral for a 15-year-old male patient who was transferred from Kaweah Delta District Hospital (KDH) to Community Regional Medical Center (CRMC) with gunshot wound to the chest. The patient received massive transfusions at KDH prior to ABO type and screen. Six days later, the patient was authorized for donation on 12-20-2020.

On 12-15-2020 at approximately 17:00, CADN received a verbal report from the KDH blood bank of ABO O Positive after massive transfusion at the time of the initial referral from CRMC. It was discovered upon case review that the CADN Clinical Procurement Coordinator (CPC) was verbally made aware of a possible weak B result from this post transfusion sample. A documented ABO from admission to CRMC was reported as O Positive. A record of all transfusions was accounted for and documented from KDH and CRMC on 12-15-2020.

At the time of donor initiation on 12-20-2020, six days following all transfusions, a repeat ABO, drawn on 12-20-2020 at 11:45, was documented from CRMC as O Positive. After donor management initiation, as per protocol, standard CADN ABO/infectious disease blood samples drawn on were sent to the VRL/Eurofins, San Ramon laboratory. The ABO was cancelled by VRL/Eurofins, San Ramon referencing the laboratory was "unable to obtain a valid result." This sample was then sent by VRL/Eurofins, San Ramon to their Denver laboratory for additional testing.

Donor management proceeded. CADN performed DonorNet ABO verification on 12-21-2020 at 13:15, as O Positive. The CADN CPC was instructed by the Clinical Operations Manager (COM) to call UNOS for ABO consultation following a discussion with the CRMC blood bank. The UNOS call concluded with UNOS' recommendation to follow OPTN policy 2.5 and 2.6. UNOS provided additional recommendations to place ABO information into DonorNet Highlights and fully disclose all ABO results to transplant centers during allocation efforts. The decision was made by CADN to continue allocation with ABO O Positive.

Allocation began on 12-21-2020 with a directed kidney donation request made from the family and match runs for heart/lung, liver and kidneys executed. CADN became aware of centers declining organs due to various reasons: size, quality and ABO information. As recommended by UNOS, all centers were updated on the ABO situation and informing the centers to reference DonorNet donor highlights. The accepting center CASF kidney transplant surgeon facilitated a phone consultation with the CRMC blood bank and CASF blood bank to verify ABO. This information was shared with accepting center CAPM simultaneous pancreas/kidney surgeon prior to recovery.

The donor was transported to the San Ramon Regional Medical Center Ambulatory Surgery Center for organ recovery. While the donor was en route, approximately two hours prior to scheduled recovery, CADN received notification from the CASU thoracic surgeon requesting a

recovery delay of two to three days for additional ABO testing. Due to CADN confidence in ABO testing resulting in O Positive, lack of available ICU space from COVID-19 virus cases, two accepting abdominal centers with blood bank expert consults, and the family concerns with overall case length, CADN decided not to accommodate the two-to-three-day delay for additional ABO testing requested by CASU and CASU declined the heart. CADN initiated expedited allocation and the heart was accepted by CASD with full disclosure of ABO during offer and prior to incision. Recovery of heart, liver, kidneys and pancreas was completed on 12-23-2020 at 06:20.

The organs were transplanted into Blood Group O recipients prior to the 12-23 2020 16:35 time referenced below.

- CASD Heart
- CASU Liver
- CASF Kidney
- CAPM SPK

CADN received the ABO result of B Positive on 12-23-2020 at 16:35 from the VRL/Eurofins, Denver laboratory from the sample sent from the VRL/Eurofins, San Ramon laboratory drawn on 12-20-2020 at 11:45. Upon receipt the following accepting transplant centers were informed of the result by CADN clinical operations staff:

- CASD Heart
- CASU Liver
- CASF Kidney
- CAPM SPK

CAPM reported verbally on 12-23-2020 at 17:39 to CADN that ABO testing on the donor blood specimen provided by CADN to CAPM with the SPK tested weakly ABO B. Documentation of a confirmed ABO result of B Positive from CAPM was received on 12-24-2020 at 11:50.

Patient outcomes were as follows:

- CASD Heart
  - The heart was removed on 12-23-2020 and placed on ECMO.
  - The patient was re-transplanted on 12-27-2020.
- CASU Liver
  - The liver is still implanted.
- CASF Kidney
  - Explanted on 12-24-2020.
- CAPM SPK
  - Explanted on 12-23-2020.

INITIAL ANALYSIS:

CADN's case review of the overall process and decision to allocate and recover this donor as O Positive identified improvement opportunities related to ABO deceased donor blood type determination and reporting.

Throughout the donor's nine-day clinical course, multiple CADN staff received and investigated information relevant to the donor's ABO. Two laboratories provided three ABO typing determinations of donor blood type as O Positive with the first sample at KWD resulting the sample as O positive with a comment of "the donor may have been B positive". This was discussed with accepting centers' transplant surgeons. The CASF transplant surgeon spoke with the CASF blood bank as well as the CRMC blood bank to review ABO typing results in the face of the donor's early multiple transfusions. Accepting center surgeons from CASF and CAPM discussed those conversations and felt comfortable moving forward. CADN staff consulted UNOS for assistance and followed disclosure instructions, however, questions remained. After two labs resulted the donor as O Positive and multiple conversations occurred with the accepting centers along with two blood banks, CADN allocated organs as blood group O Positive. A request was made by center, CASU, for additional testing which would have required a two-to-three-day delay, which CADN could not accommodate.

CADN consulted with blood specialists following the event: "The main issue in this case is the uncertainty of the donor's ABO type. He was transfused with multiple units of group O blood including 4 units of whole blood, approximating 2 blood volumes; the effect of which was to dilute his own blood to the point that testing identified circulating group O blood red cells.

Standard serologic blood typing has both a forward typing component (which tests what antigens are observed on the surface of red blood cells (RBCs) as well as a reverse typing component (which tests what antibodies are observed in the patient's plasma). The two components must match in order to unequivocally determine a blood type. This donor's forward typing at Hospital 1 showed the donor cells had no reaction with anti-A or with anti-B, which is consistent with group O RBCs in circulation. The reverse typing donor plasma reacted with reagent A cells and reagent B cells. This demonstrates the presence of anti-A and anti-B in donor circulation, which would be consistent with a group O donor. The reaction of donor plasma with type A reagent RBCs was stronger than the reaction of donor plasma with type B reagent RBCs (4+ vs 1+). This observation is congruent with the comment that the donor "may have been B pos". That comment was relevant and would have been helpful in recognizing a possible ABO discrepancy."

CADN explored "using ABO genotyping on donor derived DNA, which would be less prone to interference by transfusion. They reported being quoted a turnaround time of 3 days. Local, established ABO genotyping using RT-PCR should be able to obtain results in less than 2 hours."[1]

An initial verbal comment received from Hospital 1 suggested the donor may have been blood group B and two tests were initially resulted as invalid, but later resulted and reported as O Positive and one sample was cancelled, all due to the transfusion situation.

There are several areas for improvement which are discussed elsewhere in this document, however, the significant change that must be made is for additional and more specific testing in cases such as those described below, using donor RT-PCR ABO genotyping. CADN will add RT-PCR for donor ABO genotyping. CADN's Medical Director and Medical Advisory Board will review the revised ABO policy to require, among other changes, that ABO genotyping be performed with any of the following events:

- Massive transfusion without a pretransfusion sample.
- Result comments suggesting a different underlying type.
- Discrepancies between forward (antigen) and reverse (antibody) typing.
- Laboratories reporting invalid or inconsistent testing.

When the ABO type cannot be resolved or if there is doubt, the donor will be listed as group AB. In cases of ABO discrepancies, incomplete or invalid results not resolved by ABO genotyping, a HARD STOP will be inserted into the revised policy requiring the CADN Chief Medical Officer to have discussions with accepting surgeons.

CADN will work with blood specialists and UNOS to learn from this case and ensure that the needed policies are changed appropriately. CADN consulted with blood specialists and concurs that "Given that similar situations have occurred in the past, UNOS has recently updated their policy and guidance to include the use of ABO genotyping for identifying ABO type switching due to the transfusion and resolving discordant or unusual ABO serologic typing results. The OPO had 3 ABO determinations of group O. Although comments and invalid testing results should have raised concerns, those flags are not always available; so, they should not be relied upon to identify patients whose ABO typing may be misleading due to massive transfusions in the absence of a pre-transfusion ABO type. The relevant portion of policy states 'The host OPO must include a process to address conflicting or indeterminate primary donor type results in their written protocol.' Existing policy does not appear to explicitly address the situation where the ABO results are both resulted as group O due to massive transfusion. Individual OPO's should develop internal processes and policies to handle massive transfusion scenarios especially when the donor has received units of whole blood."[1]

[1] Expert Opinion, 1-12-2021. Requested by CADN, UNOS ID AHLS321 – ABO Mismatch.

[redacted] is the Histocompatibility Laboratory Director at Southwest Immunodiagnostics, Inc. in San Antonio Texas. She has more than 30 years of experience in histocompatibility and has served on many committees and boards for ABHI, ASHI, and other professional organizations. She is currently the past chair of the UNOS Histocompatibility Committee and serves on the Board of Directors at ASHI. Cathi served as a member of the UNOS ABO working group to develop a guidance document for ABO typing under the conditions of massive transfusion.

[redacted] is the Director for Clinical Laboratory Informatics and the Medical Director for the Tissue Typing Laboratory at Brigham and Women's Hospital. He is board-certified in Blood Banking/Transfusion Medicine, Clinical Pathology, and Clinical Informatics. He is an internationally recognized expert on blood group genotyping and is an active member of AABB, ISBT, ASHI, and was also a member of the UNOS ABO working group.

[redacted] is the Director of the Transfusion Service and of the Histocompatibility Laboratory at Loma Linda University Medical Center. He is board-certified in Histocompatibility, Blood Banking/Transfusion Medicine, Clinical Pathology, and Clinical Informatics. He is an active member of AABB and ASHI.

Attachment 7. Communication with Evaluating and Accepting Centers

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ACRONYMS:	**CADN STAFF POSITIONS:**
ASC = Ancillary Surgical Center CCT = Critical Care Transport CRMC = Community Regional Medical Center iTX = I Transplant KDH = Kaweah Delta District Hospital MTP = Massive Transfusion Protocol SRRMC = San Ramon Regional Medical Center SPK = Simultaneous pancreas/kidney TS = Type and Screen	AOD = Administrator of the Day COM = Clinical Operations Manager CPC = Clinical Procurement Coordinator DPC = Donation Program Consultant FRC = Family Resource Coordinator HDC = Hospital Donation Coordinator OAC = Organ Allocation Coordinator OPC = Organ Perfusion Coordinator

Date/Time *(Pacific Time)*	**Who/Where**	**Discussion/Notes**
12-21-2020 12:55	[redacted] (OAC) to CAIM	[redacted] (OAC) informed Conway (CAIM) of possible directed donation. CAIM to review potential recipient information for match.
12-21-2020 17:45	[redacted] (CAOP) to [redacted] (OAC)	[redacted] (CAOP) call to CADN regarding directed donation offers to CAIM. [redacted] (OAC) updates that allocation is on hold because CADN needs to speak with UNOS. CADN has multiple O Positive results, but donor could be B as updated by CRMC lab. CADN may need to re-draw tomorrow to verify and move forward.
12-21-2020 18:32	DonorNet	Kidney/Pancreas match run [redacted] – provisional offer to sequence 2 CAPM.
12-21-2020 20:16	DonorNet	Heart/Lung match run [redacted]
12-21-2020 23:22	iTX Note: [redacted] (CPC)	Entered "Pt is s/p MTP (see blood products page for quantity) with ABO resulting O+ after x2 type and screens drawn at the donor hospital. No ABO or blood samples were drawn on initial admission to hospital prior to MTP being initiated. Hospital ABO continues to result inconclusive. ID samples did not result an ABO. Per hospital trauma blood bank, when typing the pt, the red cells type as O however the serum types as B. The staff has to add more serum in order for the sample to result; The result is O+"
12-21-2020 23:37	DonorNet: Donor Highlights	Entered "Pt is s/p MTP (see blood products page for quantity) with ABO resulting O+ after x2 type and screens drawn at the donor hospital. No ABO or blood samples were drawn on initial admission to hospital prior to MTP being initiated. Hospital ABO continues to result inconclusive. ID samples did not result an ABO. Per hospital trauma blood bank, when typing the pt, the red cells type as O,

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		however the serum types as B. The staff has to add more serum in order for the sample to result; The result is O+"
12-22-2020 04:08	iTX Note: [redacted] (CPC) Thoracic Allocation	Heart: a) Primary accepting center/sequence/ surgeon: CASU seq 3 Dr. Heisinger b) Backup center/sequence/surgeon: CAUH reviewing back up offer c) Late decline details (notify COM): N/A crossmatch blood will arrive ~0320 Lungs: a) Primary accepting center/sequence/ surgeon: allocation of left lung in process b) Backup center/sequence/surgeon: allocation of left lung in process c) Late decline details (notify COM): Pending cross matches: CASU has crossmatch pending for H/Ki seq 3 Anticipated cross clamp delays: TBD once crossmatch is resulted Follow up items: continue allocation of L lung and obtain strong back up for Heart.
12-22-2020 13:53	DonorNet	Heart/Lung match run [redacted] – provisional offer to sequence 9 CASU.
12-22-2020 14:52	DonorNet	Heart/Lung match run [redacted] – Primary acceptance of heart at sequence 9 CASU.
12-22-2020 15:30	iTX Notes: [redacted] (CPC) Thoracic Allocation	Heart: a) Primary accepting center/sequence/ surgeon: CASU seq 9 b) Backup center/sequence/surgeon: CASU could possibly back up for their seq 17. CASF coded out for size on all their pts c) Late decline details (notify COM): none Lungs: a) Primary accepting center/sequence/ surgeon: N/P list exhausted b) Backup center/sequence/surgeon: n/a c) Late decline details (notify COM): n/a Pending cross matches: none Anticipated cross clamp delays: yes, one-hour Recovering surgeon: [redacted] Follow up items: none. Notified [redacted]
12-22-2020 15:38	DonorNet	Liver match run [redacted] – provisional offer sequence 36 CASU.
12-22-2020 15:41	iTX Notes: [redacted] (OAC) Directed Donation	Call from CAIM regarding directed donation that after further discussion they believe this donor is too much of risk for ABO incompatibility and declined. Did not notify anyone because felt resolved.
12-22-2020 16:15	[redacted] (OAC)	[redacted] (OAC) provides backup liver offer to CASF stating they are behind national pediatrics and CASU but getting concerns since many are declining. When asked why she states that some are concerned for CIT, size and quality which confuses [redacted]
12-22-2020 16:54	DonorNet	Liver match run [redacted] – primary acceptance of liver at sequence 36 CASU.

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12-22-2020 17:00	Crystal Sweat (OPC) [redacted] (COM)	OR Setting Huddle: Recovery location at San Ramon Regional Medical Center (SRRMC) Ancillary Surgical Center (ASC) at 2200 with recovery of heart, liver, pancreas, and kidneys.
12-22-2020 17:04	[redacted] (OAC)	Provides primary offer to [redacted] (CAPC) kidney program with discussion of ABO incompatibility concerns by CAIM. Coordinator states she will discuss with her surgeon.
12-22-2020 17:34	[redacted] (OAC) from CAPC	[redacted] (CAPC) surgeon calls in requesting further information. [redacted] (OAC) refers surgeon to [redacted] (COM) for ABO information and clarification outlined in DonorNet Donor Highlights and provides her direct phone number.
12-22-2020 17:47	DonorNet	Kidney match run [redacted] – primary offer to sequence 8.
12-22-2020 17:54	[redacted] (OAC) from CAPC	Call from CAPC kidney coordinator declining for all patients due to the blood type discrepancy. States that their surgeon spoke with [redacted] (COM) and it seems unclear what the blood type actually is. CAPC does not want to put their potential transplant recipients (PTR) at risk because of ABO discrepancy.
12-22-2020 18:54	[redacted] (OAC) to CASF	[redacted] (OAC) provides primary kidney offer to CASF/ [redacted] (OAC) discussed ABO incompatibility concerns and why other programs have declined. He requests blood bank phone number so that he can have CASF blood bank call to verify all is safe. He also requests that [redacted] call UCSF Immunogenetics and Transplantation Laboratory (ITL) to verify Human Leukocyte Antigen (HLA) is ok as well.
12-22-2020 18:58	[redacted] (OAC) to HLA lab	Call to ITL and they verify HLA is ok with described situation.
12-22-2020 19:00	[redacted] (CPC) [redacted] (CPC)	Verbal report from [redacted] (CPC) to [redacted] (CPC). Report includes discussion of ABO process and review of all documentation of testing. Also discussed the multiple huddles, communications and UNOS call resulting in listing patient as O Positive.
12-22-2020 19:04	iTX Notes: [redacted] (CPC)	Royal Ambulance (CCT) arrived at CRMC and patient was transferred to ambulance with team. No issues. Pt out the door 18:53.
12-22-2020 19:05	[redacted] (CPC)	Received phone call from CASU Thoracic surgeon, [redacted] He asked for clarification on Donor Highlight's statement regarding ABO verification to move forward with 22:00 OR. [redacted] (CPC) was just starting shift and would follow up immediately with dayshift [redacted] (CPC).
12-22-2020 19:07	[redacted] (CPC)	Called [redacted] (CPC) and received report. Informed [redacted] (CPC) of call received and [redacted] (CASU) concerns and potential to decline offer if not remedied. Made plan to have [redacted] (CPC) call [redacted] (CASU) and [redacted] (CPC) would alert [redacted] (COM) of the developing situation.

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12-22-2020 19:15	[redacted] (COM) to [redacted] (CASU)	[redacted] (COM) spoke with [redacted] (CASU) and answered questions about timing of transfusions, when ABOs were drawn, and results of ABOs. [redacted] (CASU) reiterates he may decline and that he was going to reach out to the head of the UCSF blood bank, [redacted] for guidance and requested time to facilitate those conversations.
12-22-2020 19:18	[redacted] (CPC)	Received call from [redacted] (CASU) Thoracic Coordinator. She apologized that she had not reached out prior to [redacted] (CASU). She wanted to understand what was happening and how allocation was able to proceed. I updated her with the information from UNET Donor Highlights page and let her know [redacted] (CPC) was reaching out to [redacted] (COM) while [redacted] (CPC) was calling [redacted] (CASU) back.
12-22-2020 19:22	[redacted] (CPC) [redacted] (COM)	[redacted] (CPC) called [redacted] (COM) with CASU Thoracic update. [redacted] (CPC) completed call with [redacted] (CASU) during this time and was added into the call. [redacted] informs team that CASU Thoracic requests a 2-3 day delay to complete additional ABO testing. Discussed options of patient return to CRMC or admit into SRRMC Intensive Care Unit. ASC delay would bump another CADN case scheduled donor transfer and recovery later in the morning of 12-23-2020. Due to the patient being in CCT to SRRMC ASC, a return to CRMC was not considered an option. Plan for [redacted] (COM) to contact CADN Administrator on Duty (AOD).
12-22-2020 19:29	CASF to CADN [redacted] (OAC) from [redacted]	Updated that [redacted] (CASF) has consulted head of CASF Blood Bank, [redacted] also called CRMC Blood Bank and all agree OK to proceed with donor as listed O Positive.
12-22-2020 19:34	[redacted] (AOD) [redacted] (COM)	[redacted] (COM) informed [redacted] (AOD) that CASU Thoracic concern and request for delay due to information provided in UNET Donor Highlights. CASU requested CADN hold organ recovery for two to three days to allow for additional ABO typing. AOD and COM agreed to ensure CASU was aware that donor was already in route to SRRMC ASC and that this information was posted in DonorNet prior to offers as well as the call made to UNOS. Due to CADN confidence in ABO testing resulting in O Positive, lack of available ICU space from COVID-19 virus cases, two accepting abdominal centers with blood bank expert consults, and the family concerns with overall case length, CADN decided not to accommodate the two-to-three-day delay for additional ABO testing requested by CASU and CASU declined the heart.
12-22-2020 19:39	[redacted] (AOD) [redacted] (Vice President Strategic Partnership)	[redacted] (AOD) discussed CASU decline 2 hours prior to scheduled recovery after having accepted offer at 12-22-2020 at 14:52. Plan to offer heart as open offer to local centers.

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12-22-2020 19:49	[redacted] (CPC)	Received call from [redacted] (COM) who requested that open heart offer be made to CASF, as CASU is expected to code out in the next 15min. Discussed the possibility of delaying OR by no more than 1 hr.
12-22-2020 19:52	[redacted] (OAC) to CASF Dr. [redacted]	Clarifying call to [redacted] (CASF) to confirm that blood bank representative, [redacted] CASF consulted CRMC blood bank and that the patient is correctly listed as O Positive.
12-22-2020 19:59	[redacted] (CPC)	[redacted] (CPC) called Heather Hansen (CASF) Thoracic Coordinator. Updated her on situation and gave open heart offer if heart team would be able to accommodate 22:00 OR and pending CASU formal decline. Coordinator stated that she had already coded out her top three sequences due to size and that logistically it would be impossible to get a recipient ready within the time available. [redacted] (CPC) and coordinator plan for her to reach out to surgeon for final determination.
12-22-2020 20:16	[redacted] (CPC)	[redacted] received text from [redacted] (CASF) Thoracic Coordinator that they are unable to accept heart for any of their patients due to needs, size, and timing.
12-22-2020 20:34	[redacted] (CPC)	[redacted] (CPC) received call from [redacted] (CASU) Thoracic Coordinator reporting that they are NOT coding out but will not be able to make the scheduled 22:00 incision time due to the need for ABO confirmation/verification.
12-22-2020 20:34	[redacted] (AOD) [redacted] (Donor Transfer Program Manager)	[redacted] (AOD) discussed possibility of ICU bed for the donor at SRRMC and requested call to SRRMC from [redacted] (Transfer Manager) who was informed that no ICU beds were available due to COVID.
12-22-2020 20:35	[redacted] (CPC)	[redacted] (CPC) updated by [redacted] (COM) of CADN trying to facilitate admission to SRRMC ICU to facilitate heart allocation. Updated [redacted] (COM) of last conversation with [redacted] (CASU) Thoracic Coordinator and their intent to delay OR.
12-22-2020 20:40	[redacted] (OPC) to [redacted] (COM) Statement	• [redacted] (OPC) informs [redacted] (COM) that CASD had been given an open offer and was interested in the heart. • [redacted] (COM) clarified that they made sure CASD understood why heart was declined and ensure all information was shared and reviewed. • CASD requests 20 minutes to review offer closely, donor records and all information in DonorNet. • [redacted] (COM) communicated to [redacted] (AOD) and [redacted] (VP) to update and make sure they were aware and in agreement with open offer to CASD.
12-22-2020 20:46	[redacted] (COM) [redacted] (AOD)	[redacted] (COM) updated [redacted] (AOD) that heart was offered to CASD as open offer. [redacted] (AOD) reiterated to [redacted] (COM) to make sure that CASD knew of reason that CASU was declining heart. [redacted] (COM) acknowledged and stated she would ensure they received all information related to ABO.

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12-22-2020 20:54	iTX Note: [redacted] (OPC) Late entry 12-23-2020 16:18	Spoke with [redacted] (CASD) to see if they would have any interest in the heart. [redacted] A. (OPC) explained the donor was shot in the chest and had multiple transfusions. [redacted] stated he would review all information in DonorNet. [redacted] O. (OAC) granted CASD UNET access for review of chart prior to acceptance.
12-22-2020 21:00	[redacted] (OPC) to [redacted] (COM) Statement	CASD accepts heart offer and requests OR delay to accommodate team arrival for recovery
12-22-2020 21:18	iTX Notes: [redacted] (CPC)	Royal Ambulance (CCT) arrived at SRRMC ASC with donor.
12-22-2020 21:41	[redacted] (OAC) to [redacted] (CASF)	[redacted] (OAC) call to [redacted] (CASF) to notify of OR time delay related to late heart decline r/t ABO incompatibility concern by CASU. Notifies that blood bank called second hospital, but patient received massive blood at KDH prior to being transferred. Dr. [redacted] (CASF) felt confident moving forward based on CASF blood bank consult with CRMC blood bank. [redacted] (OAC) asked [redacted] (CASF) if OAC could provide [redacted] (CASF) phone number should other centers want more information, to which he agreed.
12-22-2020 21:52	[redacted] (OAC) to Dr. William Bry (CAPM)	Update call to [redacted] (CAPM) regarding decline of heart by CASU due to concern for ABO compatibility. [redacted] (CAPM) expresses concern stating he is leaning towards not accepting unless someone convinces him he does not have to worry about the blood type of the donor. He asks whether CASF obtained a blood bank consult and requests [redacted] (CASF) contact information.
12-22-2020 Immediately following	[redacted] (CAPM)	[redacted] (CAPM) contacts [redacted] (CASF) and is briefed on UCSF blood bank consult. [redacted] (CAPM) states he is comfortable moving forward.
12-23-2020 01:00	[redacted] (CPC)	CADN OR-F-025.02 *ABO Verification and OR Time Out Checklist* signed by [redacted] (CADN Qualified Healthcare Professional).
12-23-2020 02:00	[redacted] (CPC)	Verbal report to [redacted] (CADN), abdominal recovery surgeon including review of all source documents associated with ABO (CRMC ABO X 2 and VRL cancelled). CADN OR-F-025.02 *ABO Verification and OR Time Out Checklist* signed by Dr. Kelly (CADN) 12-23-2020 at 02:00.
12-23-2020 02:23	[redacted] (CPC)	Verbal report to [redacted] (CASD), thoracic recovery surgeon, including review of all source documents associated with ABO (CRMC ABO X 2 and VRL cancelled). Dr. [redacted] (CASD) reported he was not aware of ABO situation and [redacted] (CPC) reviewed all documentation and UNET Donor Highlights with him. [redacted] (CASD) called accepting surgeon and confirmed accepting center had reviewed all ABO documents and cleared to proceed.

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		CADN OR-F-025.02 *ABO Verification and OR Time Out Checklist* signed by [redacted] (CASD) 12-23-2020 at 02:25.
12-23-2021 02:31	iTX Notes: Intraoperative Management	Incision
12-23-2020 03:24	iTX Note: Intraoperative Management	Cross clamp
12-23-2020 03:40	iTX Note: Heart Data	Heart recovered by CASD [redacted]
12-23-2020 04:02	iTX Notes: Pancreas Data	Pancreas recovered by CADN [redacted]
12-23-2020 04:03	iTX Notes: Liver Data	Liver recovered by CADN [redacted]
12-23-2020 04:10	iTX Notes: Renal Data	Kidneys recovered by CADN [redacted]
12-23-2020 04:59	DonorNet	Kidney/Pancreas match run [redacted] – primary acceptance of kidney/pancreas sequence 2 CAPM. Kidney match run [redacted] acceptance at sequence 8 CASF.
12-23-2020 06:20	iTX Notes: Intraoperative Management	Exit Operating Room
12-23-2020 10:06	CASD Thoracic to [redacted] (OAC)	[redacted] CASD) called [redacted] (OAC) to state that they were having trouble leaving the OR. Concerned that it may be ABO incompatibility, as the heart looked great upon arrival. [redacted] (OAC) stated that she had not heard of any concerns from other programs.
12-23-2020 Immediately following previous call	[redacted] (OAC) [redacted] (COM)	[redacted] (OAC) initiates immediate escalation/notification to [redacted] M. (COM).
12-23-2020 Immediately following previous call	[redacted] (OAC) [redacted] (Allocation Manager)	[redacted] (OAC) notified [redacted] (Allocation Manager) in CADN office to inform her and consult plan of action. Discussed with following plan: • [redacted] (OAC) would notify CASD that we would contact all other accepting centers to verify current patient status and notify them that the heart was not doing well with CASD's concerns for ABO incompatibility. • CADN would report to them (CASD) should any transplants appear to have any signs and symptoms of ABO incompatibility. • Any further clinical questions regarding donor would be directed to the COM and if not available [redacted] (OAC) would provide contact to [redacted] (Allocation Manager).
12-23-2020	[redacted] (OAC)	Call to Liver program (CASU). Relayed CASD patient status and their ABO incompatibility concerns, requested patient status and

Attachment 7. Communication with Evaluating and Accepting Centers

Immediately following previous call		informed patient was doing well. [redacted] (OAC) was updated that the liver can tolerate ABO incompatibility.
12-23-2020 11:00 (approximate)	Valerie Chipman (Allocation Manager) [redacted] (OAC) [redacted] (COM)	[redacted] (OAC) received more communication from CASD requesting liver biopsy from CASU to evaluate function of transplanted organ. CASD expressed concern for ABO incompatibility. Updated [redacted] M. (COM) and [redacted] (Allocation Manager).
12-23-2020 11:32	[redacted] (COM) to [redacted] (AOD)	Incoming call from [redacted] (COM) stating update received from CADN allocation coordinator that CASD recipient was not doing well. Requested that [redacted] (COM) make calls to other centers and recipients were reported as "doing fine." CASD was investigating cause of failure.
12-23-2020 11:45	[redacted] (OAC)	[redacted] (OAC) called into the SPK OR to speak with [redacted] (CAPM) to check on the case. Notified CAPM OR circulator of CASD's current situation and belief that the patient is ABO incompatible. CAPM OR Circulator placed [redacted] (OAC) on speaker and [redacted] (OAC) relayed information to team. They were right at the point of anastomosis of the pancreas. [redacted] (OAC) was asked how the liver was doing and she stated they were doing well. The transplant team had a muffled discussion and decided to proceed.
12-23-2020 12:29	[redacted] (OAC)	Contacted [redacted] (CASF) and he updated that the kidney was working fine.
12-23-2020 12:36	[redacted] (OAC)	Called CAPM and told them that she had reached [redacted] (CASF) and the kidney was working fine.
12-23-2020 12:43	[redacted] (OAC)	A different person (unidentified) from CASD called requesting information and was provided [redacted] (COM) contact information.
12-23-2020 15:26	[redacted] (OAC)	Call from [redacted] (CAPM) that SPK failed and was removed, told that [redacted] (COM) would be notified.
12-23-2020 16:16	[redacted] (OAC)	[redacted] (OAC) call to CASU's liver attending surgeon to notify of SPK failure.
12-23-2020 16:35	iTX Attachments: VRL Lab, Denver	FINAL ABO result attached to iTX from ID/ABO blood draw 12-20-2020 11:45. ABO Result B Positive.
12-23-2020 17:39	[redacted] (OAC)	Call from [redacted] (CAPM) that UNOS AHLS321 donor blood that came with SPK tested weakly ABO B at his center. Requested to speak to [redacted] (COM). Provided [redacted] (COM) contact information.
12-23-2020 18:40	[redacted] (COM) Summary of Events	• Notified by [redacted] (OAC) at 11:00 that heart recipient graft failing. • Notified by [redacted] (CASD) at 11:29 of heart recipient complications and being placed onto Extracorporeal Membrane Oxygenation (ECMO). • Request by [redacted] (CASD) at 16:00 with a request for a buccal swab from the donor for DNA ABO typing. Determined donor at [redacted] Coroner's Office. Discussed case with [redacted]

Attachment 7. Communication with Evaluating and Accepting Centers

		(AOD) and will attempt to facilitate buccal swab. [redacted] (CASD) later called and requested no DNA swab rather attempts to speak with mom surrounding donor ABO, her or father's ABO. [redacted] (FRC) made a call to mother who was unable to answer questions surrounding ABO. • 17:53 - [redacted] S. (COM) updated [redacted] (CAPM) of result. • 17:59 - [redacted] (COM) updated [redacted] [redacted] (CASD) of result. • 18:01 - [redacted] (VP Strategic Partnerships) updated [redacted] (CASF) of result. • 18:20 - [redacted] S. (COM) updated [redacted] (CASU) of result.
12-23-2020 20:45	[redacted] [redacted] (AOD) with [redacted] [redacted] (CASD)	[redacted] (AOD) spoke with [redacted]. [redacted] requested clarification on how ABO discrepancy occurred. [redacted] (AOD) informed [redacted] that we are still investigating but gave her timeline of all blood draws, what was entered into DonorNet, and advice from UNOS. Tamra questioned why the surgeon was not made aware. [redacted] (AOD) informed [redacted] that our coordinator called her coordinator [redacted] to give update on reason CASU was declining offer and coordinator stated they would look in DonorNet. [redacted] asked if all information was in donor highlights, [redacted] (AOD) explained "yes" and prior to all offers including CASU. Tamra and [redacted] (AOD) then read donor highlights together and she stated, "Oh ok, I see that now." [redacted] (AOD) informed [redacted] that we did not have the KDH ABO printout at the time of offers but it was in the donor highlights. [redacted] agreed. [redacted] stated that she would keep [redacted] (AOD) personally updated on the condition of the recipient. Results faxed to [redacted] at 21:40
12-24-2020 11:50	[redacted] (AOD) from Sutter Health CPMC	Fax received from [redacted] [redacted] CAPM Transfusion Service per [redacted] (AOD) request on ABO result from blood sample sent with SPK. Resulted as B Positive. COMMENT: Mixed field reaction with Anti-B, consistent with recent transfusion of O cells. Attached to DonorNet.

Attachment 8. SE-M-001 Infectious Disease and ABO Testing Manual

DONOR NETWORK WEST

[redacted]

Donor Network West

Infectious Disease / ABO Testing Manual

Document #: SE-M-001.06

Effective Date: 12/09/20

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1.1.5.2.1. Infectious disease testing results from shared organ donor (pre-mortem) cases are acceptable. Additional testing may be required based on processor requirements.

1.1.5.3 Organ: Timing for Obtaining, Submitting, and Testing Infectious Disease Samples

1.1.5.3.1. *Upon Authorization (BD or DCD)*– samples should be obtained, sent, and tested as soon as possible following recorded or written authorization.

1.1.5.3.2. *Prior To Authorization For Donation (BD or DCD)* –samples may be obtained, sent, and held or tested in circumstances where the results will assist with the determination of medical suitability of a potential organ donor.

- If testing a patient's blood for infectious diseases prior to authorization for donation, permission for such tests and agreement to disclose reactive results must be obtained from the attending physician. Reactive results will be placed in the patient's hospital records.
- The above communication with the attending physician will be documented in the DNWEST ELECTRONIC DONOR RECORD.
- Attachment 4.4 DNW GUIDELINES: SENDING INFECTIOUS DISEASE TESTING PRIOR TO AUTHORIZATION should be utilized to determine which potential donors qualify for testing prior to authorization.

1.1.5.4 General Sample Requirements

1.1.5.4.1. Samples should meet requirements of collection kit manufacturers and testing laboratories.

1.1.5.4.2. The sample tested shall be assessed for plasmadilution requirements as described in the Plasmadilution / Hemodilution section 1.2 below.

1.1.5.5 Tissue Sample Requirements

1.1.5.5.1. All blood samples used for infectious disease testing must be drawn within seven days prior to or after the donation. Stricter collection kit manufacturer requirements supersede this requirement.

1.1.5.5.2. If the donor is one month (28 days) of age or less, a blood specimen from the birth mother must be collected within seven days prior to or after tissue donation and tested instead of a specimen from the donor.

1.1.5.5.3. Pre-mortem samples may be utilized for testing.

1.1.5.5.4. Blood collected by other organizations such as hospitals and Coroner/MEs may be utilized for testing, provided collection methods meet the standards of testing labs and collection kit specifications.

1.1.5.6 Organ Sample Requirements

1.1.5.6.1. If HIV, HBV, or HCV cannot be run on a qualified sample, the donor must be considered PHS increased risk. Best practices include:

- If significant blood products/colloids have been given recently (in last 48 hrs and completed within last 12 hrs), blood for early ID testing (i.e. prior to brain death and authorization) should not be drawn until there is not a risk of hemodilution.
- Any time blood or associated products have been administered prior to drawing ID testing, obtain blood bank records from the lab and reconcile all units that have been released with the records of what has been administered.
- Be sure to include any infusions or transfusions that are ordered while the hemodilution review is taking place and administered before blood draw.
- When blood products/colloids have been administered, contact Resource Triage Coordinator (RTC) or Clinical Operations Manager (COM) for a secondary review – attach the blood bank record to iTx for the RTC or COM to review.
- If hemodilution is close to not qualifying- i.e. in cases where we are double and triple checking to ensure all documentation is accounted for, and the calculation is being adjusted to see when the patient actually qualifies, add a buffer of time for a safety measure (approx. 2 hrs).

1.1.5.6.2. In the event of limited sample availability, a complete panel and ABO typing may be possible from as little as one red top and one purple top tube. If volume is insufficient to run a full panel, testing will be performed in order of priority as indicated in the Organ Donor Infectious Disease Testing and Notification of Results section 1.3 below.

- If this testing is not possible on a hemodilutionally qualified sample, it must be run on a non-qualified sample.

1.1.5.6.3. If a donor is one month of age (28 days) or younger, a blood sample from the birth mother should be tested in addition to testing of the infant donor.

1.1.5.6.4. If the potential donor is less than, or equal to, 18 months and the birth mother is known to be infected with, or at high risk for, HIV, HBV, or HCV; the donor will be considered increased risk and a blood sample from the birth mother should be tested in addition to testing of the infant donor.

1.1.5.6.5. If the donor was breast fed in the previous 12 months by someone known to be infected with, or at high risk for, HIV, HBV, or HCV; the donor will be considered increased risk and a blood sample from the breast milk provider should be tested in addition to testing of the infant donor.

1.1.5.6.6. If a donor's mother or source of breast milk is tested, authorization to do so must be obtained as described in the AUTHORIZATION FOR ANATOMICAL GIFT POLICY and documented on the AUTHORIZATION FOR BIOLOGICAL MOTHER'S MEDICAL AND SOCIAL HISTORY AND BLOOD TESTING form.

1.1.5.6.7. Samples collected in tubes with alternate additives may be acceptable. Contact the testing lab to determine if samples other than those described in this section are acceptable.

1.1.5.7 Tissue Blood Sample Procurement (post-mortem)

1.1.5.7.1. Refer to COLLECTING, HANDLING, AND SHIPPING OF SPECIMENS for blood draw procedures.

1.1.5.7.2. Specimen collection kits are provided to all Recovery Coordinators (RC) via the DNWest satellite offices (refer to infectious disease sample collection kit).

1.1.5.7.3. Verify that blood specimen tubes are not expired.

1.1.5.7.4. Collect 4 red/gray specked w/gel filter (SST) and 1 purple (EDTA) top tubes to ensure adequate plasma and blood volumes for testing, confirmatory tests, and archival.

- Consult the Administrator on Call (AOC) or designee in cases of low volume not sufficient to perform testing.

1.1.5.7.5. Blood tubes shall be prioritized in the following order:

- SST
- EDTA
- SST
- Coroner/ME samples, if applicable
- SST
- SST

1.1.5.8 Organ Blood Sample Procurement (pre-mortem)

1.1.5.8.1. Specimen collection kits are provided to all on-site coordinators via the DNWest satellite offices (refer to infectious disease sample collection kit).

1.1.5.8.2. Verify that blood specimen tubes are not expired.

1.1.5.8.3. Collect 2 red (no additive) and 2 purple (EDTA) top tubes to ensure adequate blood and plasma volumes for testing, confirmatory tests, and archival.

1.1.5.8.4. One additional purple top (EDTA) tube, sent with a second requisition form, is required if ABO sub-typing will be performed and must be drawn at a separate time from the first purple top.

1.1.5.8.5. In situations where sample volume is limited, tubes are filled and submitted in the following priority:

- Red top
- EDTA
- Red top
- EDTA
- EDTA -drawn at separate time from initial purple top if blood group A (AB is optional).

1.1.5.8.6. Blood drawn using hospital-supplied blood tubes (e.g. admit blood) is acceptable, provided sample requirements are met. In situations when the potential donor is within the jurisdiction of the Coroner/ME, and only a small aliquot of pre-transfusion serum is available, the on-site coordinator shall address sharing of the sample with the Coroner/ ME office and document this situation in the DNWest narrative note.

1.1.5.9 General Labeling Requirements for Blood Specimen Tubes

1.1.5.9.1. Blood tubes should be labeled utilizing the donor hospital labels, DNWest generated label template (see Attachment 5.3 TEMPLATE FOR BLOOD AND SPECIMEN LABELS or TransNet generated labels. The labels must include:

- Donor's full first and last name or initials (trauma designation is acceptable);
- Date of birth (mm/dd/yy);
- Date and time the sample was drawn;
- UNOS number or DNWest assigned identification number;
- Place the VRL accession barcode label on each blood tube that corresponds with the barcode label on the testing requisition form.

1.1.5.9.2. If necessary, add this information to the labels by hand printing.

1.1.5.9.3. **Organ Note:** For pediatric donors requiring testing of the mother, the mother's specimen and the requisition form needs to be labeled with the mother's name and in parentheses "mother of _____" after her name. The label of the mother's specimen must also include the donor's UNOS ID or DNWest assigned identification number.

1.1.5.9.4. **Tissue Note:** Samples that are spun and placed into aliquot tubes by RCs need to be labeled with the following information utilizing the DNWest generated label template (see Attachment 5.4 TEMPLATE FOR ALIQUOT BLOOD TUBE LABELS.)

- DNWest assigned identification number;
- Date and time sample was drawn;
- Specimen type "plasma" or "serum";
- Tube color;
- VRL accession barcode label.

1.1.5.10 Complete the ORGAN OR TISSUE DONOR INFECTIOUS DISEASE AND ABO TESTING REQUISITION FORM

1.1.5.10.1. Complete the ORGAN OR TISSUE DONOR INFECTIOUS DISEASE AND ABO TESTING REQUISITION FORM. Select testing as indicated on the form and refer to the ORGAN OR TISSUE DONOR INFECTIOUS DISEASE TESTING AND NOTIFICATION OF RESULTS POLICY.

1.1.5.10.2. Completed requisitions will be retained in the donor record and attached to the ELECTRONIC DONOR RECORD where appropriate.

1.1.5.10.3. Enclose a copy of the completed form(s) in the collection kit.

1.1.5.11 Package and Ship Samples

1.1.5.11.1. Follow the instructions provided in the collection kit to pack the samples. Refer to attachment 5.5 VRL WET ICE SHIPPER PACKING INSTRUCTIONS.

1.1.5.11.2. All samples for infectious disease testing will be hand delivered, couriered, or shipped to the testing facility.

1.1.5.11.3. For organ donors; the Allocation Donation Coordinator (DC) will notify the on-call laboratory personnel of the estimated time of arrival of the sample and document date and time sample(s) were sent in the ELECTRONIC DONOR RECORD.

1.1.5.12 Laboratory Processing

1.1.5.12.1. Organ ID testing holds:

- The testing lab will be notified by the DC if the sample is to be held for later processing.
- Each sample's hold status (yes or no) and the first and last name of the laboratory staff notified to run will be documented in the ELECTRONIC DONOR RECORD by the DC.

1.2 PLASMADILUTION – HEMODILUTION

1.2.1 INTRODUCTION AND OVERVIEW

1.2.1.1 This section describes the process for determining if blood samples for infectious disease testing are diluted by infusions or transfusions to a degree that could affect testing results.

1.2.1.2 This process applies to all organ and tissue donors.

1.2.1.3 The tissue banks and all establishments for which tissues or corneas are recovered will make the final determination of specimen suitability based on their established policies.

1.2.2 RESPONSIBILITIES

1.2.2.1 Donation Coordinators

1.2.2.2 Recovery Coordinator Team Leaders

1.2.2.3 Organ Donation Services Staff

1.2.2.4 Donor Record Coordinators

1.2.3 ATTACHMENTS

1.2.3.1 4.12 LIST OF COMMON BLOOD PRODUCTS, COLLOIDS, AND CRYSTALLOIDS

1.2.4 DOCUMENTATION / FORMS

1.2.4.1 SE-F-016 HEMODILUTION ASSESSMENT

1.2.4.2 **Organ Plasmadilution:** [iTx > Organ tab > Hemodilution > Preliminary Hemodilution Worksheet]

1.2.4.3 **Tissue Preliminary Plasmadilution**: [iTx > Tracking tab > Preliminary Hemodilution > Preliminary Hemodilution Worksheet]

1.2.4.4 **Tissue Secondary Plasmadilution**: [iTx > Tissue tab > Hemodilution > Transfusion/Infusion – Hemodilution Worksheet]

1.2.4.5 **Blood Product/Colloid Administration**: [iTx > Tissue tab > Blood Product > Blood Product /Colloid Administration Summary]

1.2.4.6 **Increased Risk Donor Disclosure Form:** [iTx>Placement tab > High Risk Donor Form > Increased risk donor disclosure form]

1.2.5 PROCESS

1.2.5.1 General Considerations

1.2.5.1.1. All samples used for required screening tests must be assessed for hemodilution according to this procedure.

1.2.5.1.2. Autologous Infusions

- If applicable, banked autologous blood must be included in the plasmadilution assessment.
  - The time between when blood was banked and when donation occurred may affect how the infused blood is factored into calculations.
  - If autologous blood was infused and calculations indicate plasmadilution to a degree that will affect viral marker test results, identify whether another draw time is possible or other samples are available.

1.2.5.1.3. Non-banked autologous (autotransfusion) blood does not need to be included in plasmadilution calculations. Note that if blood cells are returned to a donor after treatment with a "cell saver," the amount of crystalloid and colloid infused with the saved cells must be included in the plasmadilution assessment.

1.2.5.2 Organ Donor Plasmadilution

1.2.5.2.1. Organ donor plasmadilution is assessed within the DNWest Electronic Donor Record System (iTransplant). If said system is not functioning, assess plasmadilution using the Tissue Donor Plasmadilution process described in the Plasmadilution – Hemodilution section 1.2 of this document.

1.2.5.2.2. Whenever possible, pre-transfusion blood is to be used for infectious disease testing. If not available and the first sample is a not qualified specimen, a repeat test may be ordered (see Organ Donor Plasmadilution Timing and Sample Selection below). If more than one sample is used for infectious disease testing, each sample shall be qualified according to the established algorithm. Complete duplicate assessment(s) in iTransplant or use additional HEMODILUTION ASSESSMENT form(s), as applicable.

1.2.5.3 Organ Donor Plasmadilution Timing and Sample Selection

Plasmadilution for organ donors should be performed prior to blood draw using an estimated sample draw date and time.

1.2.5.3.1. If the sample will qualify, proceed with blood draw and sample submission for testing.

1.2.5.3.2. If the sample will not qualify, initiate a huddle with involved staff (onsite coordinators, RTC, COM, DC) to consider the optimal testing strategy based on risk, family and hospital time constraints, donor stability, etc. Possible testing strategies include but are not limited to:

- Consider delaying draw until a time when specimen will qualify. It is advised to draw blood safely beyond the administration of significant volumes of blood and colloids to account for potential hospital record keeping errors.
- Draw and submit sample for testing at this point and consider redraw and testing of a qualified sample prior to allocation.

  Note: refer to Obtaining and Submitting Infectious Disease Samples in section 1.1 for further clarification.

1.2.5.4 Organ Donor Plasmadilution Process

1.2.5.4.1. If donor is older than 12 years of age and there is no indication that extravascular blood loss has occurred, the sample is not considered hemodiluted.

- Examples of extravascular blood loss include internal bleeding, events such as an aortic aneurysm, trauma, or laceration with blood loss, surgical procedures, etc.
- Closed head injury or intracranial hemorrhage, in the absence of surgical intervention, is not considered extravascular blood loss.

1.2.5.4.2. Ensure all infusions and transfusions administered to the patient are recorded in iTransplant.

- All transfusions must be entered accurately with the actual amount of blood or blood product transfused, when available, and not estimated pack volume. This means that if a unit of blood is hung a few minutes outside of the required plasmadilution assessment time window, much of the blood would likely need to be factored into the assessment.
- It is often necessary to review several sources of infusion and transfusion information to obtain a complete and accurate account. For example, in the event of a trauma case with extensive infusions, it may be necessary to review paramedic / Life Flight records, hand written ED "encounter level" documents, the electronic medical record, and blood bank records to account for all blood and blood products. Many hospitals do not attach hand written records to a patient's electronic medical record until a patient is discharged (pronounced).
- If assessing plasmadilution before blood draw to determine when a sample will qualify, be sure to include any infusions or transfusions that are ordered while the hemodilution review is taking place and will be administered before blood draw.
- iTransplant pulls transfusions from other areas of the application into the hemodilution feature to perform calculations.
  - Navigate to the *Organ Plasmadilution* page within iTransplant.
  - Ensure the patient's age, weight, and gender are entered.
  - Enter the date and time the sample for testing was/will be drawn.
  - Indicate if the sample is pre or post transfusion.
  - Verify that the list of blood and colloids transfused in the 48 hours prior to sample draw is accurate.
  - Manually determine the amount of crystalloids infused in the one (1) hour prior to sample draw and enter it in the *Total Volume of Crystalloids Infused in Last Hour* section of iTransplant.
- Generally, medications do not need to be included as separate volume entries because their volume is insignificant and will not affect sample qualification.
- If donor's Total Plasma Volume/TPV (compared to colloid and crystalloid total volumes) and Total Blood Volume/TBV (compared to blood products, colloid, and crystalloid total volumes) are both within 500 mLs of being non-qualified, include medications of significant volume (i.e. $\geq$25 mLs) that are administered intravenously in the one (1) hour prior to sample draw [e.g. pre-filled syringes (amp) of D50 (glucose) or $NaHCO_3$ (bicarbonate)].
  - Crystalloids administered with medication (carriers) should also be included.

1.2.5.4.3. iTransplant will perform plasmadilution calculations and indicate sample qualification status.

1.2.5.4.4. Save the record in iTransplant by selecting the "Save" button at the bottom.

1.2.5.4.5. Another plasmadilution may be calculated on another sample by selecting the arrow button at the top of the worksheet to go to a new blank "page."

1.2.5.4.6. For *Qualified* Samples:

- No additional action is needed. Infectious disease testing is considered accurate.

1.2.5.4.7. For *Non-Qualified* Samples:

- Verify accuracy of infusions and transfusions.
- Attempt to locate or draw another sample for testing that is qualified.
- If no qualified sample can be located for HBV, HCV, and HIV testing, the donor must be considered PHS Increased Risk. The *Increased Risk Donor Disclosure Form* must be completed in iTransplant.

1.2.5.5 Tissue Donor Plasmadilution – Hemodilution

1.2.5.5.1. Tissue donor hemodilution assessment is performed to qualify samples for testing. They are not intended to account for every infused or transfused product (i.e. medications). Final determination of tissue donor sample qualification is not performed by DNWest. Final determination is performed by cornea and tissue processing establishments that make eligibility determinations prior to distribution.

1.2.5.5.2. Tissue Preliminary Plasmadilution: Tissue donor preliminary hemodilution assessment shall be performed and documented within iTransplant to qualify blood samples for infectious disease testing. These amounts are based on information available at the time of tissue donor screening. You must assess preliminary plasmadilution using the HEMODILUTION ASSESSMENT paper form if iTransplant is not available or when screening a maternal blood sample (iTx autopopulates weight of the potential donor into the calculation, not the weight of the mother).

- On shared organ donor cases, the *Organ Plasmadilution* page in iTransplant may be used as the Preliminary Hemodilution.
- The tissue recovery team may verify sample qualification at the time of recovery.
- This form does not need to be revised as additional information is obtained after preliminary hemodilution assessment (e.g. when hospital medical records are obtained by the Donor Information Team). Preliminary hemodilution is based on screening information and a *Tissue Secondary Plasmadilution* form will account for additional information.

1.2.5.5.3. Confirm the patient's age and weight are documented

- In iTransplant, navigate to the *Referral Worksheet* page [TRACKING tab > REFERRAL WORKSHEET] and confirm gender.
- On HEMODILUTION ASSESSMENT form, page 1 (only to be used when iTransplant is not accessible or when screening a maternal blood sample).

1.2.5.5.4. Determine the Hemodilution Assessment Time Period

- In iTransplant, navigate to the *Tissue Preliminary Plasmadilution* page.
- On HEMODILUTION ASSESSMENT form, page 1 (only to be used when iTransplant is not accessible).
- Record the date and time of blood sample collection. If sample is to be collected post mortem, document time of cardiac death or select asystole (post mortem sample) if using iTransplant.
- If sample to be tested was drawn before the donor's cardiac death, plasmadilution assessment will be based on the 48 hour time period preceding the date and time of blood draw. Tested sample must not be drawn greater than 7 days prior to tissue donation.
- If sample to be tested was drawn after the donor's cardiac death, plasmadilution assessment will be based on the 48 hour time period preceding the date and time of cardiac death. Tested sample must not be drawn greater than 7 days after the tissue donation.

1.2.5.5.5. In section A: record the volume of blood products that contain blood cells transfused in the 48 hour period prior to blood draw. If the sample is post-cardiac death, record the volume transfused in the 48 hour period prior to cardiac death.

1.2.5.5.6. In section B: record the volume of colloids or plasma transfused in the 48 hour period prior to blood draw. If the sample is post-cardiac death, record the volume transfused in the 48 hour period prior to cardiac death.

1.2.5.5.7. In section C: record the volume of crystalloids infused in the one (1) hour period prior to blood draw. If the sample is post-cardiac death, record the volume in the one (1) hour period prior to cardiac death.

1.2.5.5.8. In section D - Determination of Eligibility:

- On *Hemodilution Assessment* form: 1) is the TPV assessment and 2) is the TBV assessment.
- If answers to both 1) and 2) are "Yes", sample qualifies and is acceptable for infectious disease testing.
- If the sample is determined to qualify for testing, then tissue recovery may proceed.
- If answer to either 1) and/or 2) is "No", sample may not qualify and may not be acceptable for infectious disease testing.
- If the donor's age is greater than 12 years and no extravascular blood loss is known or suspected, the sample still qualifies. Consider contacting tissue processors to determine if they will accept infectious disease results from this sample.
- If extravascular blood loss is known or suspected, or the donor is 12 years or younger, a different qualified sample may be located.

1.2.5.6 Tissue Secondary Plasmadilution

1.2.5.6.1. A secondary calculation may be performed (based on cornea and tissue processor preference) and documented using the HEMODILUTION ASSESSMENT form to qualify each blood sample used for infectious disease testing. This will be initiated during the donor record coordinator review process for donor record completion and information sharing. The following guidelines will be used to complete the secondary assessment.

- All calculations will start in the algorithm on page 1 of the paper HEMODILUTION ASSESSMENT form. Page 2 of the Hemodilution Assessment Form (Transfusion/Infusion - Hemodilution Worksheet) may either be completed electronically or on page 2 of the Hemodilution Assessment form.

1.2.5.6.2. Follow decision tree/algorithm on page 1 of the Hemodilution Assessment form. Note that the following circumstances will require further calculation.

- Adult Donors: Plasmadilution sufficient to affect the results of infectious disease testing where blood loss is known or suspected in a donor over 12 years of age should be considered in the following situation:
  - The donor received more than 2000 mLs of any combination of blood products or colloids (within 48 hours of draw/cardiac death) and/or crystalloids (within 1 hour from draw/cardiac death).
- Blood Loss: examples of extravascular blood loss include internal bleeding events such as an aortic aneurysm, trauma, or laceration with blood loss, surgical procedures, etc.
- Closed head injury or intracranial hemorrhage, in the absence of surgical intervention, is not considered extravascular blood loss.

1.2.5.6.3. Pediatric Donors: Plasmadilution sufficient to affect the results of infectious disease testing regardless of the presence or absence of blood loss, in a donor 12 years of age or younger in the following situation:

- The donor received more than 2000 mLs of any combination of blood products or colloids (within 48 hours of draw/cardiac death) and/or crystalloids (within 1 hour from draw/cardiac death).

1.2.5.6.4. Transfusion / Infusion – Hemodilution Worksheet: if the decision tree/algorithm on the Hemodilution Assessment form indicates that further calculation is required, follow the steps below:

- Record the volume of blood products that contain blood cells transfused in the 48 hour period prior to blood draw. If the sample is post-cardiac death, record the volume transfused in the 48 hour period prior to cardiac death.

Note: in iTransplant, this information is transferred from the *Blood Product / Colloid Administration* page. This page needs to be completed in order for section A to populate.

- Record type of blood product. See attachment 4.12 LIST OF COMMON BLOOD PRODUCTS, COLLOIDS, AND CRYSTALLOIDS for examples.
- Record date and time of transfusion.
- Record volume transfused.
- Total and record the volume of blood products transfused.

1.2.5.6.5. Record the volume of colloids or plasma transfused in the 48 hour period prior to blood draw. If the sample is post-cardiac death, record the volume transfused in the 48 hour period prior to cardiac death.

In iTransplant, this information is transferred from the *Blood Product / Colloid Administration* page. This page needs to be completed in order for section B to populate.

- Record type of colloid. See attachment 4.12 LIST OF COMMON BLOOD PRODUCTS, COLLOIDS, AND CRYSTALLOIDS for examples.
- Record date and time of transfusion.
- Record volume transfused.
- Total and record the volume of colloids transfused.

1.2.5.6.6. Record the volume of crystalloids infused in the one (1) hour period prior to blood draw. If the sample is post-cardiac death, record the volume infused in the one (1) hour period prior to cardiac death.

- Record type of crystalloid.
- Generally, medications do not need to be included as separate volume entries because their volume is insignificant and will not affect sample qualification.
- Record volume infused.
- Total and record the volume of crystalloids infused.

1.2.5.6.7. For referrals where LTKA is being used as time of death instead of asystole or cross-clamp: If a donor is found down and was administered crystalloids (by emergency responders) more than one (1) hour after the LTKA.

- In iTransplant: Check the "PTA" (prior to arrival) box. Crystalloids entered in a line on which the PTA box is checked do not need to be administered within one (1) hour from the recorded time of death to be included in the hemodilution calculation.
- On Page 2 of the HEMODILUTION ASSESSMENT form: the crystalloids can be manually added to the form and included in the hemodilution calculation, even if the crystalloids were not administered within one (1) hour from the recorded time of death.

1.2.5.6.8. Record the donor weight. Units must be in kilograms to complete calculations (kg = lbs÷2.20462). If there are discrepancies in donor weight, use the most recent actual weight. If an actual weight is not available, use the most conservative (lightest) estimated weight.

Note: the kg to lbs conversion in iTransplant may calculate different results than the conversion listed above due to additional decimals within the calculation.

1.2.5.6.9. Calculate donor's total plasma volume (TPV) by dividing the donor's weight in kg by 0.025 (kg/0.025).

1.2.5.6.10. Calculate donor's total blood volume (TBV) by dividing the donor's weight in kg by 0.015 (kg/0.015).

1.2.5.6.11. Analyze Plasmadilution Information

- Determine if total colloid volume transfused plus total crystalloid volume infused is greater than, or equal to, donor's total plasma volume.
  - If "No", sample may qualify, see TBV calculation as well to determine if the sample is acceptable for infectious disease testing.
  - If "Yes", sample does not qualify and may not be acceptable for infectious disease testing.

- Determine if total blood products transfused plus total colloid volume transfused plus total crystalloid volume infused is greater than, or equal to, donor's total blood volume.
  - If "No", sample qualifies and is acceptable for infectious disease testing (provided answer to question above is "No" as well).
  - If "Yes", sample may not qualify and may not be acceptable for infectious disease testing.
- If donor's TPV (compared to colloid and crystalloid total volumes) and TBV (compared to blood product, colloid, and crystalloid total volumes) are both within 500 mLs of being non-qualified, include medications of significant volume (i.e. >25 mLs) that are administered intravenously in the one (1) hour prior to sample draw or cardiac death [e.g. pre-filled syringes (amp) of D50 (glucose) or $NaHCO_3$ (bicarbonate)].
  - Crystalloids administered with medication (carriers) should also be included.

1.2.5.6.12. If sample may not qualify, notify establishments that received tissue or are known to have recovered tissue from the donor. Notification should also be made to management, as applicable. Identification of an alternate sample should be attempted.

1.2.5.6.13. Sign and date to indicate completion of Hemodilution Assessment.

1.2.5.7 Tissue processing establishments may determine that additional circumstances indicate hemodilution.

1.3 DONOR INFECTIOUS DISEASE TESTING AND NOTIFICATION OF RESULTS

1.3.1 INTRODUCTION AND OVERVIEW

1.3.1.1 This section describes the requirements for donor infectious disease testing, interpretation of test results, and communication of results.

1.3.1.2 This section applies to all organ and tissue donors.

1.3.2 RESPONSIBILITIES

1.3.2.1 This section applies to all DNWest staff responsible for organ and tissue services.

1.3.3 ATTACHMENTS

- 4.3 Infectious Disease Checklist
- 4.4 DNW Guidelines: Sending Infectious Disease Testing Prior to Authorization
- 4.5 Infectious Disease Testing Table
- 4.6 HIV Testing Interpretation Guidelines
- 4.7 Hepatitis B Testing Interpretation Guidelines
- 4.8 Hepatitis C Testing Interpretation Guidelines
- 4.10 Work Instructions – Use of The Reactive Infectious Disease Notification List – Portal
- 4.11 Reflex Testing Tables

1.3.4 DOCUMENTATION / FORMS

1.3.4.1 Reactive Infectious Disease Notification List – Portal

1.3.4.2 Donor Network West Electronic Donor Record (electronic donor record)

1.3.4.3 DI-F-012 Notification of Significant Finding

1.3.4.4 SE-F-017 Organ Donor Infectious Disease and ABO Testing Requisition Form

1.3.4.5 SE-F-018 Tissue Donor Infectious Disease and ABO Testing Requisition Form

1.3.4.6 SE-F-019 Organ Donor Culture Testing Requisition Form

1.3.5 PROCESS

1.3.5.1 General Considerations

1.3.5.1.1. All DNWest organ and tissue donors shall be tested for infectious disease and notifications of reactive results will be made as required by applicable regulations, laws, and standards.

1.3.5.1.2. Tissue: DNWest does not determine donor eligibility. All test results are forwarded to establishments that recovered tissues from the same donor or that received tissues recovered by DNWest. DNWest interprets results relative to donor ineligibility as described in this procedure in an effort to promptly notify applicable establishments, State officials, and donor families and discard tissues in possession, known to be unsuitable for transplant.

1.3.5.2 Archived Samples

1.3.5.2.1. Sera or plasma from every recovered donor, if available, shall be archived for a period of at least 10 years after the recovery, collection, or acquisition date. Refer to the EF-P-017 SERUM ARCHIVE POLICY for further details.

1.3.5.3 Organ Testing

1.3.5.3.1. Routine Testing

- Testing indicated in attachment 4.5 INFECTIOUS DISEASE TESTING TABLE should be performed on all donors. Equivalent tests may be substituted for those listed when warranted.
- If sample volume is insufficient to perform all testing, prioritize as indicated in the table.
- If testing is not possible on a hemodilutionally qualified sample, it must be run on a non-qualified sample.

1.3.5.3.2. Required Testing

- HIV antibody (anti- HIV) or HIV antigen/antibody (Ag/Ab)
- Hepatitis B surface antigen (HBsAg)
- Hepatitis B core antibody (HBcAb)
- Hepatitis C antibody (anti-HCV)
- Hepatitis C ribonucleic acid (RNA) or nucleic acid test (NAT)
- Syphilis (VDRL or RPR)
- Cytomegalovirus (CMV) antibody (anti-CMV)
- Toxoplasma Immunoglobulin G (IgG) antibody
- Epstein-Barr Virus (EBV) antibody (anti-EBV)
- West Nile Virus (WNV) antibody; (not required by UNOS)
- West Nile Virus (WNV) nucleic acid test (NAT); (not required by UNOS)
- Coccidioides antibody (not required by UNOS)
- If a donor is identified as being at increased risk for HIV, HBV, and HCV transmission according to PHS guidelines, testing must include NAT HIV or HIV Ab/Ag unless the following is true:
  - The donor has already been tested for HIV using HIV Ag/Ab combination test.
  - The donor's only increased risk factor is having received hemodialysis within the past 12 months.

1.3.5.3.3. Tests From Hemodiluted Samples

- If HIV, HCV, and/or HBV tests are run from a blood sample that is hemodiluted, the donor must be considered increased risk by PHS Guidelines and transplant centers must be notified.

1.3.5.3.4. Additional Tests

- Additional testing will automatically be performed when pre-determined reactive results scenarios occur as indicated in attachment 4.11 REFLEX TESTING TABLES.
- Testing in addition to reflex testing may be performed as warranted.
  - The need for additional testing for Strongyloides, and Chagas are based on responses to the UDRAI and/or presenting symptoms or diagnostic findings. The COM is consulted in these cases and documented in the ELECTRONIC DONOR RECORD.
  - Testing for respiratory syncytial virus (RSV) and Influenza A and B will be conducted at DNWest's contracted testing facility or the donor hospital based on responses to the UDRAI and/or presenting symptoms and documented in the ELECTRONIC DONOR RECORD.
- Additional testing is performed to:
  - Estimate the accuracy of required test results (e.g. false or true reactive);
  - Help determine if a reactive result indicates a transmissible disease (e.g. past exposure or active infection);
  - Provide additional information for a donor's personal representative, should notification be warranted.

1.3.5.4 Tissue Testing

1.3.5.4.1. Routine Testing

- For post-mortem samples, testing shall be done using donor screening tests specifically labeled for cadaveric specimens instead of a more generally labeled donor screening test, when applicable and when available.

1.3.5.4.2. Required Testing

- Antibodies to the human immunodeficiency virus, type 1 and type 2 (anti HIV-1 and anti-HIV-2)
- Nucleic acid test (NAT) for HIV
- Hepatitis B surface antigen (HBsAg)
- Total antibodies to hepatitis B core antigen (anti HBc—total, meaning IgG and IgM)
- Nucleic acid test (NAT) for hepatitis B virus (HBV)
- Antibodies to the hepatitis C virus (anti-HCV)
- Nucleic acid test (NAT) for HCV
- Syphilis (a non-treponemal or treponemal-specific assay may be performed).

1.3.5.4.3. Additional Tests

- Human T-lymphotropic virus type I and type II (anti-HTLV-I and anti-HTLV-II) is only required for donors if leukocyte rich tissues will be transplanted. Processing establishments may request this testing depending on tissue type, processing method, and testing requirements where tissue will be transplanted (e.g. international).
- Additional tests may be run on a case-by-case basis (e.g. upon processing establishment request).

1.3.5.5 Results

All results will be retained as a permanent part of the donor's record.

1.3.5.5.1. Organ Results

- Interpretation of reactive, positive, and indeterminate results are indicated in attachment 4.5 INFECTIOUS DISEASE TESTING TABLE.
  - *All positive / reactive results, regardless of confirmatory / reflex testing and possible interpretations, MUST be communicated verbally to each accepting transplant center at the time of organ offer and included in donor highlights.*
- Note that these tables show common results scenarios. Not all tests listed will be available for every donor, and additional tests and results scenarios are possible. The Chief Medical Officer (CMO) and / or Infectious Disease Consult may be contacted at any time to answer questions or to provide advice about serologic test results.
- Results must be interpreted using source documentation (i.e. fax or scan of the laboratory's report). Verbal results or transcriptions of results from test reports are not acceptable.
  - Delays in reporting, which may result from reactive test results followed by subsequent testing, should be reported immediately to the DC with an estimated time to expect results.
  - Delays in testing that might impact organ recovery should be reported immediately to the DNWest COM, RTC and/or AOC.

1.3.5.5.2. Tissue Results

- A donor shall be determined ineligible, and tissue from that donor shall be determined not suitable for transplant, if the donor's sample tests repeatedly reactive for anti-HIV-1, anti-HIV-2, HBsAg, anti-HBc total, anti-HCV; anti-HTLV-I, or anti-HTLV-II. When a birth mother's specimen is used for testing, these same rules apply.
- A donor shall be determined ineligible and tissue from that donor shall be determined not suitable for transplantation if the donor's sample tests positive, repeat reactive, or repeatedly reactive on a screening test using a NAT assay listed in this section. When a birth mother's specimen is used for testing, these same rules apply.
- Tissue from a donor reactive for syphilis using an FDA-licensed, cleared, or approved non-treponemal screening assay may be used for transplantation if the sample is found to be negative using an FDA-

licensed, cleared, or approved treponemal-specific confirmatory assay. A specific example is when a syphilis agglutination test is initially reactive, an FTA may be performed on the same sample and if negative, the donor may be eligible.

- If a laboratory performs initial testing in triplicate for an organ donor, results of all three tests must be obtained and the donor determined ineligible, and tissue from that donor determined not suitable for transplantation, if any one of the three tests is reactive.
- If results of additional infectious disease testing are received for tests that are not required or described in this document, such tests must be considered when determining the donor's eligibility. Forward results to other establishments involved in recovery or processing of tissues from the affected donor.

1.3.5.5.3. Documenting and Reporting of Results

- All infectious disease testing information is considered confidential and not suitable for public disclosure of any type. Any disclosure of the results other than for the purpose of evaluating donor suitability, allocating organs, alerting hospital staff, reporting to government agencies as required by law, or notification of the personal representative or designee is a violation of DNWest's confidentiality policy. Requests for release of infectious disease results (other than those indicated above) shall be brought to Quality Systems management.
- Upon receipt of confirmed reactive infectious disease testing results, enter relevant information into the REACTIVE INFECTIOUS DISEASE NOTIFICATION LIST -PORTAL as described in attachment 4.10 WORK INSTRUCTIONS – USE OF THE REACTIVE INFECTIOUS DISEASE NOTIFICATION LIST – PORTAL.
- Upon receipt of testing results for organ donors, the DC shall attach the results into the DNWEST ELECTRONIC DONOR RECORD and the UNET donor record and make the following notifications:
  - Clinical Procurement Coordinator (CPC) to be notified immediately. The COM must be notified of positive infectious disease results as indicated in attachment 4.5 INFECTIOUS DISEASE TESTING TABLE.
- Prior to the completion of a DC's shift, and within 24 hours of receipt of initial reactive infectious disease results, the DNWest Aftercare Team and Quality Systems Department shall be notified of all positive infectious disease results indicated in attachment 4.5 INFECTIOUS DISEASE TESTING TABLE. This will ensure appropriate follow up and County notification.

1.3.5.6 Reporting to Other Organ and Tissue Banking Establishments

1.3.5.6.1. All testing results are routinely shared with establishments that recover organs or tissues from a DNWest donor or process tissues recovered by DNWest.

1.3.5.6.2. For reactive results (e.g. repeat reactive, repeatedly reactive, positive), all organizations involved in organ or tissue recovery, or processors that have received tissues recovered by DNWest, shall be notified of the repeat reactive results within one working day of receipt of the test results.

1.3.5.7 Reporting to the State of California

1.3.5.7.1. Counties of the State of California shall be notified of confirmed reactive results as described in Title 17, California Code of Regulations, Sections 2502 and 2641.5-2643.20.

1.3.5.8 Family Notification

1.3.5.8.1. In cases where testing occurs prior to authorization, DNWest does not authorize or disclose donation, and the attending physician has agreed to disclose results to the family; reactive results will be reported to the patient's attending physician to be added to the hospital record.

1.3.5.8.2. If notification by Aftercare or DNWest clinical personnel is warranted, as indicated in attachment 4.9 GUIDELINES FOR VERBALLY NOTIFYING PERSONAL REPRESENTATIVE OF REACTIVE INFECTIOUS DISEASE RESULTS, DNWest will notify the donor's personal representative. Notification will be made whether or not reactive infectious disease test finding(s) determine(s) medical unsuitability of the donor (an Authorization Not Recovered - ANR).

1.4 LOGISTICS

1.4.1 INTRODUCTION AND OVERVIEW

1.4.1.1 The purpose of this section is to establish a consistent method for the logistics of specimen processing, packaging, and delivery to the VRL-Eurofins satellite location at DNWest's Norris Canyon facility in San Ramon.

1.4.2 ORGAN PROCESS

1.4.2.1 Kits

1.4.2.1.1. Kits for infectious disease testing are assembled by Facilities and logged in to the BTM inventory system. Kit types include ambient and wet ice shippers.

- Ambient shippers are to be utilized in cases where the specimen can reach the testing lab within 6 hours of blood draw (e.g. Bay and Modesto regions).
- Wet ice shippers are to be utilized in cases where the specimen will reach the testing lab more than 6 hours after the blood draw (e.g. Northern, Fresno, and Reno regions).

1.4.2.1.2. The onsite coordinator assigns individual ID testing kits to a specific donor case via the BTM system.

1.4.2.2 Notification and Delivery of ID Testing Samples

1.4.2.2.1. All specimens for ID testing are collected, labeled, and packaged by the onsite coordinator. The onsite coordinator notifies the DC in the Operations Center that a courier is required for specimen pickup.

1.4.2.2.2. The DC arranges for courier pick-up from the originating hospital and delivery to the testing lab via Airspace Technologies' online system. (Note: Airspace Technologies will be the primary courier. Alternate couriers may be utilized if Airspace is not available.)

- Job set up includes pickup and destination locations. Airspace is responsible for all logistics of transportation between pickup and final destination (including flights and additional drivers as needed).
- Communication between DNWest and Airspace occurs via push notifications from the online system and direct phone calls, when needed in cases where special handling instructions need to be conveyed.
- Tracking of the specimen occurs on the Airspace website. All drivers are geo-located, and the information is fed directly to the online system specific to the job.
- Notification that a specimen is en route is made by the DC via email to the testing lab to supportSR@vrl-eurofins.com.
  - The testing lab ideally requires a 2-hour notification in order to allow reagents to come to room temperature prior to testing.
- The following documentation relating to ID testing shall be recorded in the ELECTRONIC DONOR RECORD by the DC:
  - Date/time samples sent
  - Job number
  - Estimated date/time of sample arrival
  - Actual date/time of sample arrival
  - Lab tech notification method (email) and date/time
- Upon arrival to the testing facility, the courier will enter through the designated courier area and notify the lab via phone call that the specimen has arrived.
  - During business hours, Facilities staff may be required to sign for samples.
  - Outside of business hours, VRL will receive a courier call for sample pickup in the courier room.

1.4.2.3 Notification of ID Testing Results

1.4.2.3.1. Notification of pending and final results are communicated to the DC via email by VRL-Eurofins.

1.4.2.3.2. The DC will attach the results to the ELECTRONIC DONOR RECORD and DonorNet.

1.4.2.3.3. The DC notifies the onsite coordinator that results have been uploaded.

1.4.3 TISSUE PROCESS

1.4.3.1 Procurement of Specimen

1.4.3.1.1. Once blood is obtained, placed into the appropriate tubes, and labeled, the blood is then placed in the recovery cooler until tissue procurement is complete.

1.4.3.2 Processing and Shipment/Delivery

Processing of the specimen prior to packaging and method of delivery to the testing lab are dependent on the geographic location of the donor.

1.4.3.2.1. Recovery at DNWest Norris Canyon Facility or Recovery Locations with Return to Norris Canyon

- Processing of the specimens by the RC is not required. The specimens are to be placed in a biohazard bag and the completed requisition is to be placed in the pocket of the bag. The specimen will be hand delivered to the testing lab.

1.4.3.2.2. Satellite Recovery Locations Requiring Shipment

- Upon return to the satellite office, specimens will be spun and placed in aliquot tubes and labeled. The processed specimens will be packaged in wet ice shippers. Multiple donor specimens can be placed in a single wet ice shipper (approximately 3 donors or the equivalent of 12 tubes).
- Redding and Reno locations: once packaged and ready for shipment to the testing lab, the technician will arrange for pickup either via FedEx or DNWest driver.
- Fresno location: once packaged and ready for shipment to the testing lab, the RC will place the package in the FedEx pickup area. Daily pickup by FedEx will occur at the designated times.
  - DNWest drivers can be utilized when appropriate.
  - QUICK service can be utilized when FedEx pick-up is not available in a timely manner.

1.4.4 VRL-EUROFINS SPECIMEN PROCESSING

1.4.4.1 Stat testing runs will be started 1.5 – 2 hours following receipt of the samples or sooner if there is sufficient advance notice of specimen arrival.

1.4.4.1.1. Additional testing requests can be made by the DC via email after consultation with the COM and/or onsite coordinator.

1.4.4.2 Testing specimens can be held for up to 48 hours only, or must be aliquotted and frozen within 48 hours, to facilitate the full testing panel.

1.4.4.3 Non-stat testing runs will be on a production cycle and will occur at 0600, 1400, and 0000.

1.4.4.4 Fail over / power outage equipment battery backup is good for 30 minutes. This should enable VRL to safely remove samples from equipment and ship to their backup testing facility.

2.0 ABO & SUBTYPE TESTING

2.1 ABO AND SUBGROUP TESTING AND VERIFICATION

2.1.1 INTRODUCTION AND OVERVIEW

2.1.1.1 The purpose of this section is to describe the DNWest policy which mandates the determination of two separate blood group determinations on all potential organ donors in compliance with UNOS/OPTN policy.

2.1.1.2 This procedure applies to all potential organ donors.

2.1.1.3 Allocation of organs will be based on the donor's primary blood type without consideration of subtyping in the following instances:

2.1.1.3.1. Pretransfusion specimens are not available

2.1.1.3.2. The laboratory is unable to interpret results

2.1.1.3.3. Subtyping results are discrepant

- Hospital ABO subtype (if applicable)
- All Infectious Disease testing lab subtypes

2.1.1.3.4. Allocation has begun prior to subtype results being confirmed

2.1.2 RESPONSIBILITIES

Qualified Health Care Professionals (QHCP) - Organ Program staff responsibility to:

2.1.2.1 Obtain and verify two separate determinations of the donor's blood type (and subtype, if applicable) prior to match run.

2.1.2.2 Use the source documents to enter and verify the donor's blood type (and subtype, if applicable) in the DNWEST ELECTRONIC DONOR RECORD and UNET.

2.1.2.3 Verify online the donor blood type (and subtype, if applicable).

Note: this must be done by an individual other than the person initially entering the data.

2.1.2.4 Document the double verification of a donor's blood type (and subtype, if applicable) and have the documentation available for review by the United Network for Organ Sharing (UNOS).

2.1.2.5 Convey the blood group to UNOS and to transplant center personnel.

2.1.3 ATTACHMENTS

- 4.1 ABO SUBTYPE REQUIREMENTS AND RESULTS ALGORITHM

2.1.4 PROCESS

The DNWest on-site coordinator shall be responsible for obtaining two separate ABO determinations, and subtype if indicated, that meet the following requirements:

2.1.4.1 OPTN/UNOS Guidelines: Subtyping is required when the following three conditions are met:

2.1.4.1.1. The donor is more than 3 years old;

2.1.4.1.2. The donor's ABO blood type is A (AB is optional); and

2.1.4.1.3. Both subtype determinations can be made on pre-transfusion samples (transfusion of blood or blood products in the previous 120 days can affect results; however, plasma or platelets will not affect the determination of the A subtype).

2.1.4.2 Two separate samples for ABO and subtyping must be taken on two separate occasions, defined as: one draw and then another draw after 5 minutes or more of elapsed time.

2.1.4.2.1. **Note:** All available typing and subtyping results must be assessed and found to be equivalent (e.g. hospital results, first laboratory result, second laboratory result).

2.1.4.2.2. **Note:** For all blood type A donors, documentation in the ELECTRONIC DONOR RECORD will be completed indicating either subtyping was completed, or the reason why it could not be completed.

2.1.4.2.3. **Note:** Historical blood type results can be used for one of the typings if source documentation of these results is available.

2.1.4.3 Documentation of the laboratory initial and confirmatory tests will be maintained in the ELECTRONIC DONOR RECORD.

2.1.4.4 Upon receipt of the ABO typing, the DC will register the donor in the DonorNet system.

2.1.4.5 The DC will attach the UNET Donor Summary Screenshot to the ELECTRONIC DONOR RECORD. The on-site coordinator will verify the UNET Donor Summary Screenshot.

2.1.4.6 Prior to initiating DonorNet match runs, a second DNWest coordinator, who is a QHCP, will verify the donor's ABO and subtype (if applicable) from two separate sources, drawn on two separate occasions, and submitted as separate samples using source documents in DonorNet.

2.1.4.6.1. Verification will be documented in the ELECTRONIC DONOR RECORD.

2.1.4.6.2. If a discrepancy exists between the source documents, an additional sample for ABO determination will be obtained and tested at the donor hospital, or other designated testing site, in an attempt to resolve the discrepancy.

- Guidelines for Handling Conflicting Primary Blood Type Results in section 2.2 will be used in an attempt to resolve the discrepancy.

2.1.4.7 Upon recovery team arrival and prior to incision, the on-site coordinator, who is a QHCP, will review the entire donor record and will verify the donor ID, ABO and subtype (if applicable), and organs to be recovered (including laterality) using source documents and acceptable sources, with each lead recovery surgeon/personnel.

2.1.4.8 The VERIFICATION OF ABO AND OR TIME OUT CHECKLIST will be signed by the on-site coordinator and each lead recovery surgeon/personnel.

2.1.4.9 A copy of page one of the signed VERIFICATION OF ABO AND OR TIME OUT CHECKLIST form with the ABO Verification section completed will be:

2.1.4.9.1. Included in the donor record that accompanies each organ;

2.1.4.9.2. Attached to the ELECTRONIC DONOR RECORD; and

2.1.4.9.3. Attached in DonorNet.

2.2 GUIDELINES FOR HANDLING CONFLICTING PRIMARY BLOOD TYPE RESULTS

2.2.1 INTRODUCTION AND OVERVIEW

2.2.1.1 The purpose of this section is to ensure recipient safety by establishing a consistent method for addressing and resolving conflicting primary blood type results which may occur when the donor has been subjected to blood transfusions that result in sero conversion.

2.2.2 PROCESS

2.2.2.1 Should two separate primary blood type results conflict, the following steps should be taken:

2.2.2.1.1. Initiate an additional blood type test at the donor hospital in an attempt to resolve the discrepancy.

- A primary blood type conducted prior to any transfusion should be used as the standard for matching.
- Historical blood type results can be used for one of the typings if source documentation of these results is available.

2.2.2.1.2. Obtain an additional typing specimen and send it to an outside lab for testing.

2.2.2.1.3. If no blood transfusions were administered and a discrepancy between the two primary results still exists, two additional separate samples will be drawn at two separate times and submitted for typing as two separate specimens to two separate labs.

2.2.2.2 If unable to resolve the discrepancy, a huddle to establish a plan will be held with the CMO, COM, DC and onsite coordinator. An Administrator may be contacted as needed.

2.2.2.3 The plan can include the following guidelines for resolving hemodilution.

2.2.2.3.1. When efforts to resolve the discrepancy have been exhausted, the following match run sequence should take place with the more restrictive blood type to be utilized for the match run. A pre-transfusion specimen should be used as the standard for the match run. Situations in which this would occur include blood transfusions administered via massive transfusion protocol prior to, and/or in between, blood draws.

- A blood type and O blood type = match run on A blood type.
- B blood type and O blood type = match run on B blood type.
- A blood type and B blood type = match run on AB blood type.
- A blood type and AB blood type = match run on AB blood type.
- B blood type and AB blood type = match run on AB blood type.
- O blood type and AB blood type = match run on AB blood type.
- Should the A subtype be in conflict, then the donor will be considered to be A1 or A1B as appropriate.

2.2.2.4 Document and communicate the plan as follows:

2.2.2.4.1. Document the plan in the progress notes of the electronic donor record.

2.2.2.4.2. Verbally communicate the plan to all receiving transplant centers.

2.2.2.4.3. Include a statement in Donor Highlights section of DonorNet. Samples:

- Donor with UNOS ID WXYZ123 has an undetermined ABO after multiple testing attempts. We have conferred with our Medical Director and decided to identify the donor as type X. This is the most restrictive type indicated by the incongruent results. Recipients matching the blood type as listed should be compatible regardless of how the results are interpreted.
- Donor with UNOS ID WXYZ123 has an undetermined ABO after multiple testing attempts. We have conferred with our Medical Director and opted to identify the donor as type AB to minimize risk of incompatibility given recipients on the match should be AB and "universal recipients" with immunologic compatibility to any ABO.

2.2.2.4.4. Print multiple copies of the statement for use in the Operating Room. Attach copies to ABO verification paperwork (e.g. ABO VERIFICATION AND OR TIME OUT CHECKLIST and VERIFICATION OF LABELING AND PACKAGING form) and include copies with source ABO documents that accompany each organ.

2.2.2.4.5. Attach results of every ABO test to DonorNet and include results of every ABO test with each organ.

3.0 FORMS / JOB AIDS

DO NOT USE -- FOR REFERENCE ONLY!

ACCESS ORIGINALS FROM THE SHAREPOINT DOCUMENT CONTROL LIBRARY (SDCL) AND THE JOB AIDS SECTION OF THE DNW PORTAL.

3.1 SE-F-016 HEMODILUTION ASSESSMENT

Form

DONOR NETWORK WEST

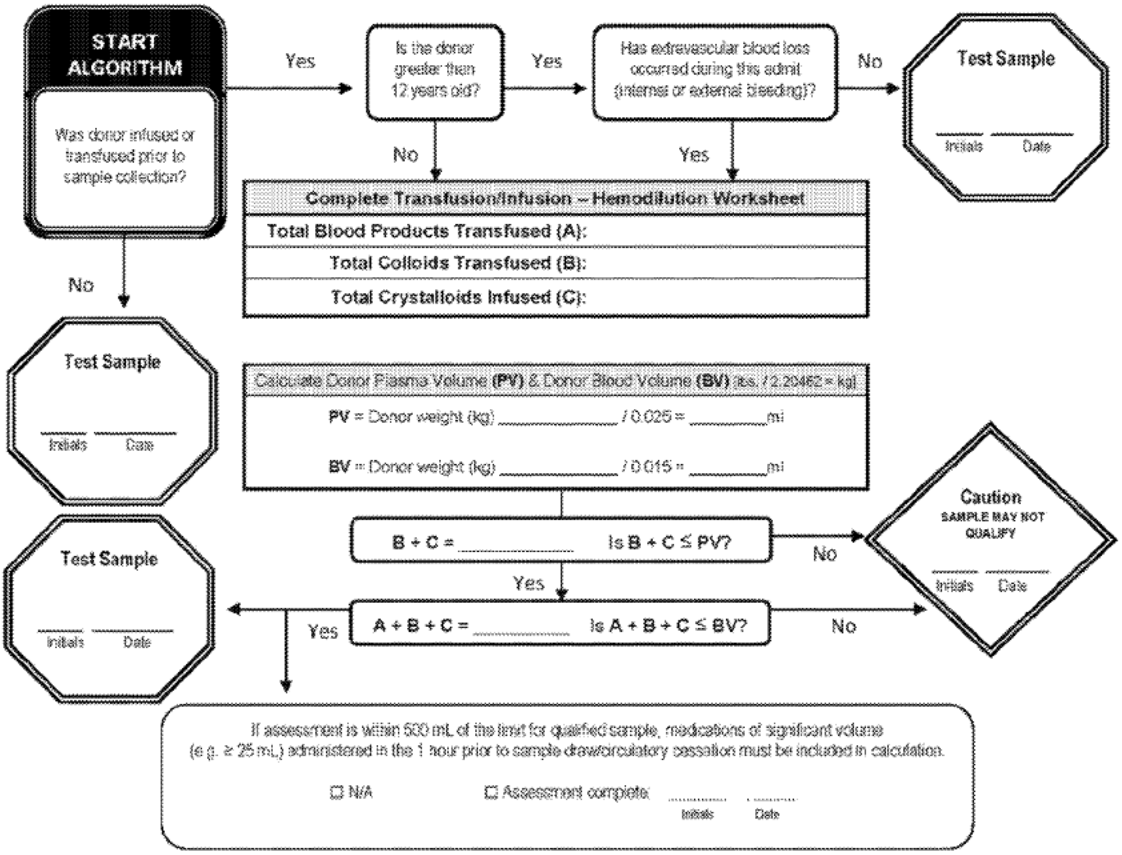
Title: Hemodilution Assessment		
Document Number: SE-F-016.01	Page Number: 1 of 2	Effective Date: 12/03/18

Donor Name or ID #

Cardiac Death Date Time ☐ N/A Maternal	Sample Draw Date Time Drawn by

REMINDER: SAMPLE MUST BE DRAWN WITHIN 7 DAYS OF THE DATE OF TISSUE DONATION

Assessment Time Period Based On: ☐ Cardiac Death Time (if sample was collected post mortem) ☐ Sample Collection Time (if sample was collected before CTOD)



Comments: ☐ N/A

Hemodilution Algorithm Performed by:

Printed Name Signature Date

Form

DONOR NETWORK WEST

Title: Hemodilution Assessment		
Document Number: SE-F-016.01	Page Number: 2 of 2	Effective Date: 12/03/18
Donor Name or ID #		

Transfusion/Infusion – Hemodilution Worksheet

The documentation on this page is:
- ☐ N/A – see page 1
- ☐ N/A - see electronic Transfusion/Infusion – Hemodilution Worksheet
- ☐ Applicable – see below

Record volume of **blood products** transfused during the 48 hours before sample was drawn (or cardiac death if drawn post cardiac death)

BLOOD CELL PRODUCTS: – PRBCs – Re-constituted blood – Whole Blood

Blood Product	Date / Time	Volume
Total Blood Products Transfused in 48 Hours **(A)**:		

Record volume of **colloids** transfused during the 48 hours before sample was drawn (or cardiac death if drawn post cardiac death)

COLLOIDS / PLASMA:
- – Albumin*
- – Dextran
- – Hespan
- – Hetastarch
- – Viaspan
- – Platelets
- – FFP
- – Cryoprecipitate

*For 25% albumin, minimum volume to be used in this calculation is 70 mL, even if a lesser amount is documented in medical records

Colloid	Date / Time	Volume
Total Colloids Transfused in 48 hours **(B)**:		

Record volume of **crystalloids** infused during the 1 hour before sample was drawn (or cardiac death if drawn post cardiac death)
Include medications of significant volume (e.g. ≥ 25 mL) if assessment is within 500 mL of the limit for a qualified sample

CRYSTALLOIDS: – D/W – Lactated Ringers – Normal Saline

Crystalloid	Date / Time	Volume
Total Crystalloids Infused in 1 Hour **(C)**:		

3.2 SE-F-017 ORGAN DONOR INFECTIOUS DISEASE AND ABO TESTING REQUISITION FORM (with Job Aid)

VRL | Eurofins Pre-Transplant Testing

APPLY ACCESSION # BARCODE LABEL HERE

VRL SUPPORT: 925-574-6041

PRIMARY/BILL TO CLIENT			IDENTIFICATION INFORMATION
☒	ACCOUNT#: [redacted]	ACCOUNT NAME : Donor Network West - Organ	(DONOR ID LABEL)
TESTING RUN			REFERRAL ID / UNOS NUMBER
TEST RUN: ☒ STAT ****Please email SupportSR@vrl-eurofins.com for these submissions****			

SAMPLE INFORMATION

TOTAL # OF SAMPLES		COLLECTION COUNTY	
TIME ZONE:	☐ EST ☐ CST ☐ MST ☒ PST ☐Other_____	**PACKAGED** DATE / TIME:	**SHIPPER TYPE:** ☐ Wet Ice ☐ Anthem ☐ Nano ☐Other:

SAMPLE INFORMATION	TRANSFUSION STATUS	COLLECTION DATE	COLLECTION TIME	CENTRIFUGE DATE	CENTRIFUGE TIME	REFRIGERATION DATE	REFRIGERATION TIME	FROZEN DATE	FROZEN TIME
☒ Pre-Mortem ☐ Post-Mortem ☐ Living	☐ Pre ☐ Post ☐ Post (no RBCs)								
☒ Pre-Mortem ☐ Post-Mortem ☐ Living	☐ Pre ☐ Post ☐ Post (no RBCs)								
☒ Pre-Mortem ☐ Post-Mortem ☐ Living	☐ Pre ☐ Post ☐ Post (no RBCs)								

PROFILE REQUESTED	ABO SUBTYPE *If yes, an additional purple top & 2nd requisition form is required
☐ **P3920 Organ Donor Profile:** HBsAg, HBc Total Ab, HCV Ab, HIV 1/2 Plus O Ab, CMV IgG, RPR, ABO/Rh (plus subtype as applicable), HIV-1/HCV/HBV NAT, EBV IgG, WNV NAT, WNV Ab (10), WNV IgM), Toxo IgG, Coccidioides Ab ☐ **126:** Coccidioides Ab	☐ 1400: ABO/Rh (plus subtype as applicable) **AGE RELATED & STUDY TESTS** Donors age 10-55 years (if unable to perform at hospital lab) ☐ 49: HgA1C Donors ≥ 30 years old ☐ 3546: nPOD

SUPPLEMENTAL TESTS (Confirm need for supplemental tests prior to ordering based on answers to Uniform DRAI & Addendum)

Donors born in or resided 3 or more consecutive months in Latin America (Mexico, Central or South America)	Donors born in or resided 3 or more consecutive months in areas identified for Strongyloides
☐ 3224: Chagas Screen	☐ 188: Strongyloides Ab (IgG)

Donor Network West Coordinator Completing Form: _____

VRL USE ONLY

Tube A:_____ Tube B:_____ Tube C:_____ Tube D:_____ Tube E:_____ Tube F:_____ Other:_____

SE-F-017.03 Organ Donor Infectious Disease and ABO Testing Requisition Effective: 06/19/19

2341 09.24.2019 #TAS

Completing the VRL Organ Donor Infections Disease and ABO Testing Requisition

About

The form SE-F-017, Organ Donor Infectious Disease and ABO Testing Requisition, is a PDF fillable form. To use, open the form from document control and begin typing into the grey boxes. Each grey box indicates a fillable field. In the event that you are not able to use the fillable form on a computer, printing the form and hand filling the information would also be acceptable.

Completing the Form

Field	Information to enter
Identification Information	Place the donor ID label here (use the same label as the one on the specimen tubes).
Referral ID	Place the DNWest referral ID number here. Note: this will allow for automatic upload to iTransplant
UNOS Number	If available, place the UNOS number here
Total # of samples	Indicate the number of tubes being sent to VRL for testing
Collection County	Indicate the county from which the specimen was acquired (i.e. Alameda)
Packaged Date/Time	Use the date drop down menu or type in the date with the format MM/DD/YYYY and use military time (HH:MM)
Shipper Type	Indicate shipper type being utilized • Ambient for specimens reaching lab within 6 hours of draw time • Wet Ice for specimens reaching lab greater then 6 hours after draw time
Transfusion Status	"Pre" – donor did not receive blood products or colloids prior to blood draw "Post" – donor did receive blood products or colloids prior to blood draw "Post (no RBCs)" – donor received plasma or platelets only prior to blood draw
Collection	Use the date drop down menu or type the date with the format MM/DD/YYYY and use military time (HH:MM)
Centrifuge	N/A to organ donor specimens unless submitting a hospital acquired sample that has been spun down

Updated 04.11.19

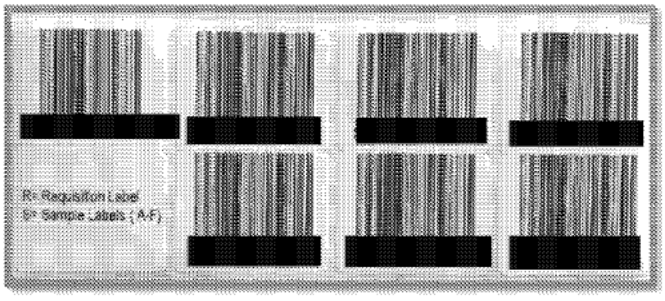
DONORNETWORKWEST.org

Field	Information to enter
Refrigeration	N/A to organ donor specimens unless submitting a hospital acquired sample that has been refrigerated
Frozen	N/A to organ donor specimens unless obtaining a hospital acquired sample that has been frozen
Profile Requested	Select the Organ Donor Profile for all donors • Note: ABO & subtype (if applicable) are embedded in the profile (VRL automatically tests for subtype for A & AB donors w/no RBCs administered) • Exception is if second requisition for subtype only • Select Coccidioides Ab for all donors
ABO Subtype	To be utilized for second requisition only where subtype verification is needed on all A or AB donors who have not received RBCs prior to ID testing draw
Age Related & Study Tests	Check HgA1C for donors between the age of 10 – 55 only if the hospital is unable to perform this test Check nPOD on all specimens submitted if the potential donor is age 30 or less
Supplemental Tests	Check the appropriate box if applicable based on donor demographics/presenting symptoms (check with COM prior to ordering)
Donor Network West Coordinator Completing Form	Enter your first and last name

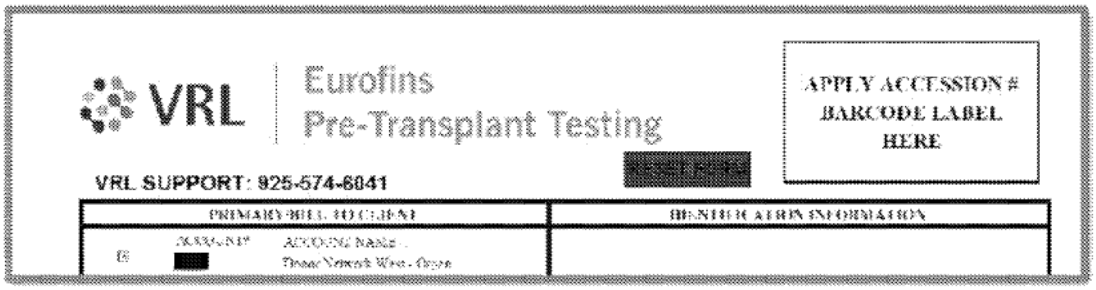
Once all fields are filled, print the completed form. Click the "Reset Form" button if a second requisition needs to be completed. See attachment on last page for example of a completed form.

Using Accession Labels

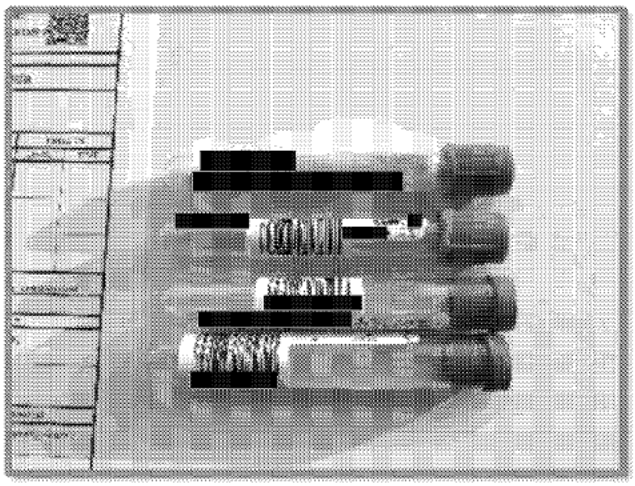
After labelling the blood tubes per policy, obtain a sheet of VRL accession labels



Place the accession barcode label that starts with "R" on the upper right corner of the printed requisition form.



Place one accession barcode label that starts with "S" vertically on each blood tube. Vertical placement ensures easier scanning for VRL lab staff.

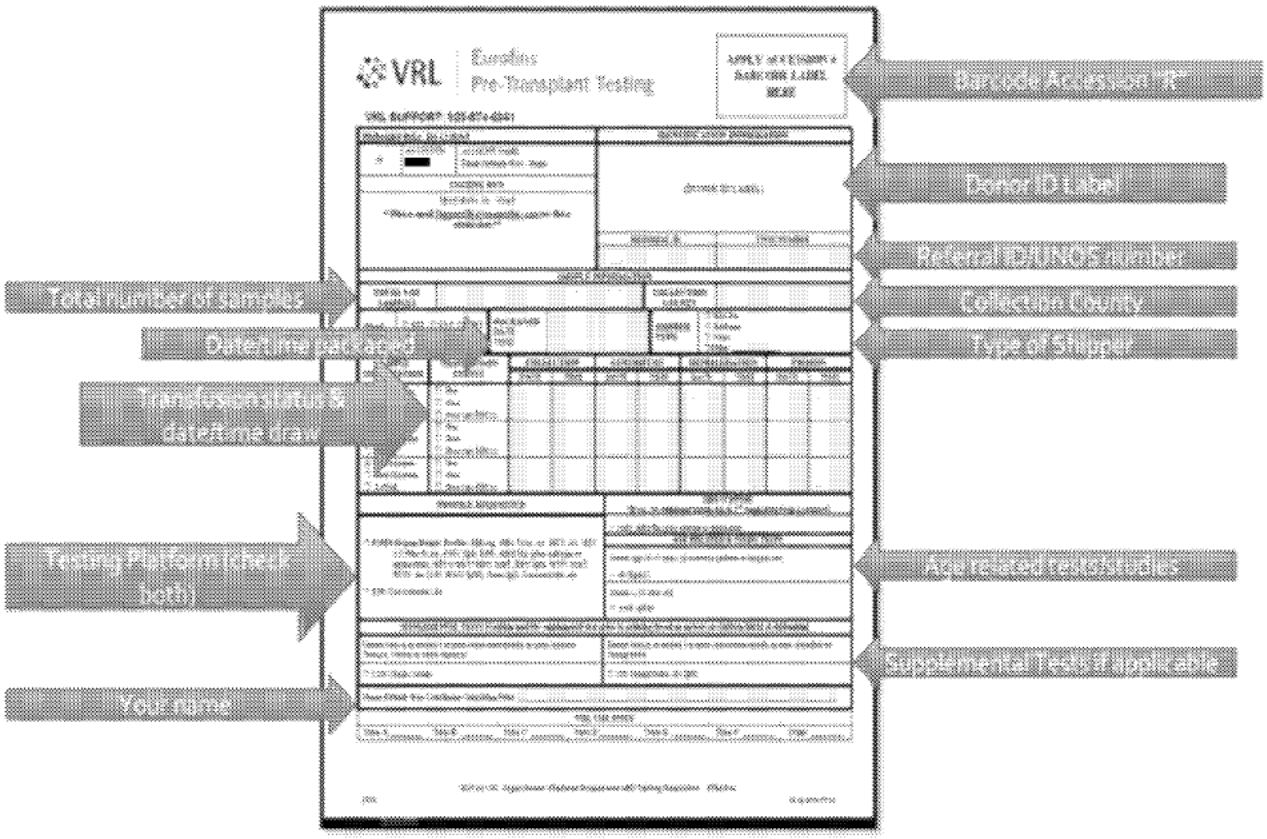


Updated 04.11.19

DONORNETWORKWEST.org

Example: Organ Donor Infectious Disease and ABO Testing Requisition

- Calendar drop down for date
- Military time oo:oo format



3.3 SE-F-018 TISSUE DONOR INFECTIOUS DISEASE AND ABO TESTING REQUISITION (with Job Aid)

VRL | Eurofins Pre-Transplant Testing

APPLY ACCESSION # BARCODE LABEL HERE

VRL SUPPORT: 925-574-6041 RESET

PRIMARY/BILL TO CLIENT			IDENTIFICATION INFORMATION		
	ACCOUNT#	ACCOUNT NAME :	DONOR ID		
☒	[redacted]	Donor Network West	DATE OF BIRTH	AGE	GENDER

SAMPLE INFORMATION

TEST RUN: ☒ ROUTINE

****Please email Support@vrl-eurofins.com if samples will be submitted STAT****

TOTAL # OF SAMPLES		TIME ZONE:	☐ EST ☐ CST ☐ MST ☒ PST ☐Other_____	PACKAGED DATE / TIME:		Shipper Type:	☐ Wet Ice ☐ Ambient ☐ Nano ☐Other:

SAMPLE INFORMATION	TRANSFUSION STATUS	COLLECTION		CENTRIFUGE		REFRIGERATION		FROZEN	
		DATE	TIME	DATE	TIME	DATE	TIME	DATE	TIME
☐ Pre-Mortem ☐ Post-Mortem ☐ Living	☐ Pre ☐ Post								
☐ Pre-Mortem ☐ Post-Mortem ☐ Living	☐ Pre ☐ Post								
☐ Pre-Mortem ☐ Post-Mortem ☐ Living	☐ Pre ☐ Post								

PROFILE REQUESTED	REPORTS TO BE PROVIDED TO:
☐ **3348: Without HTLV:** HBsAg, HBc Total, HCV, HIV 1&2, RPR, HIV/HCV/HBV NAT ☐ **3469: With HTLV:** HBsAg, HBc Total, HCV, HIV 1&2, HTLV I/II, RPR, HIV/HCV/HBV NAT	☐1367 CryoLife ☐1366 LifeCell ☐1418 AlloSource ☐1526 LifeNet ☐1525 MTF ☐1695 Sightlife ☐2345 CTS: Dayton Partners ☐2634 Aziyo Biologics, Inc. ☐1600 CorneaGen – Richmond

INDIVIDUAL TESTS

☐ 0014: ABO/Rh	☐ 3212: HBc IgM	☐ 3504: CMV IgG	☐ 3214: HBsAg	☐ 3521: HIV 1&2	☐ 3546: HTLV I/II	☐ 3722: WNV NAT
☐ 3513: EBV IgG	☐ 3213: HBs Ab	☐ 3211: HBc Total	☐ 3221: HCV	☐ 3551: RPR	☐ 3588: Chagas	☐ 3770: HIV/HCV/HBV NAT

Donor Network West Coordinator Completing Form: _____

Tube A: _____ Tube B: _____ Tube C: _____ Tube D: _____ Tube E: _____ Tube F: _____ Other: _____

TR-F-012.01 Tissue Donor Infectious Disease and ABO Testing Requisition Effective: 04/19/2019

2240

04.16.2019 IFT/MTS

Completing the VRL Tissue Donor Infectious Disease and ABO Testing Requisition

About

The form TR-F-012, Tissue Donor Infectious Disease and ABO Testing Requisition, is a PDF fillable form. To use, open the form from document control and begin typing into the grey boxes. Each grey box indicates a fillable field and should not be left blank. In the event that you are not able to use the fillable form on a computer, printing the form and hand filling the information would also be acceptable.

Completing the Form

Field	Information to enter
Donor ID	DNWest donor ID number
Additional ID #1 and #2	"N/A"
Date of Birth	use the format MM/DD/YYYY
Age	use a 2-digit number; if less than a year the unit of time measurement
Gender	indicate "F" or "M"
Test Run	check "routine"
Total # of samples	indicate the number of tubes being sent to VRL for testing
Packaged Date/Time	use the date drop down menu or type in the date with the format MM/DD/YYYY and use military time (HH:MM)
Shipper type	indicate "wet ice" unless an alternative shipper type is being used
Sample information	– Post-mortem blood draw – check "Post-Mortem" – Pre-mortem donor sample – check "Pre-Mortem" – Maternal blood sample – check "Living"
Transfusion status	– Donor received blood, blood products or colloids prior to blood draw – check "Pre" – Donor did not receive blood, blood products or colloids prior to blood draw – check "Post"
Collection	use the date drop down menu or type the date and time that the sample was drawn using the date format MM/DD/YYYY and using military time (HH:MM)

Updated 05.30.2019

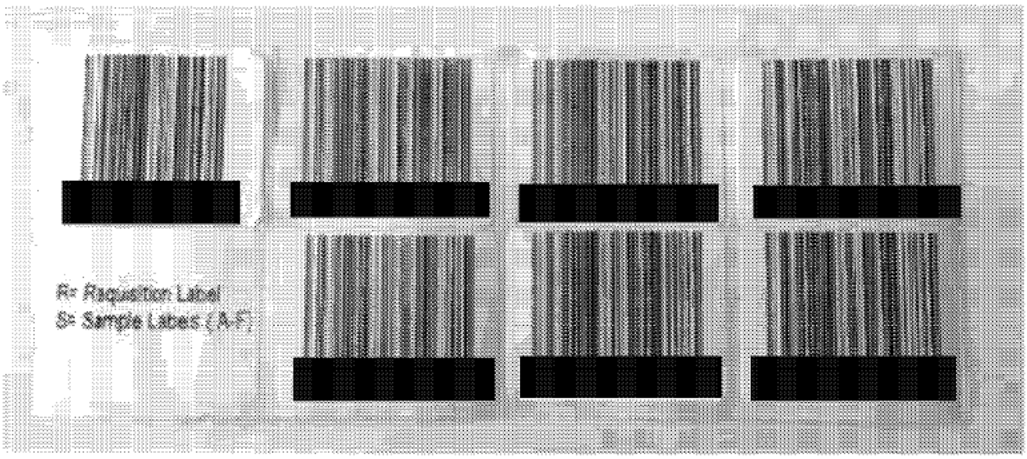
DONORNETWORKWEST.org

Field	Information to enter
Centrifuge	use the date drop down menu or type the date and time that the sample was spun using the date format MM/DD/YYYY and using military time (HH:MM), if the tubes were not spun hand write "N/A" on the form after it is printed
Refrigeration	use the date drop down menu or type the date and time that the sample was placed on ice using the date format MM/DD/YYYY and using military time (HH:MM), if the tubes were not refrigerated hand write "N/A" on the form after it is printed
Frozen	use the date drop down menu or type the date and time that the sample was frozen using the date format MM/DD/YYYY and using military time (HH:MM), if the tubes were not frozen hand write "N/A" on the form after it is printed
Profile Requested	reference the job aid "Selecting a Serology Panel" and select the appropriate test panel for your case
Reports to be Provided To	check the box(es) for the processor(s) that is(are) receiving tissue from this donor
Individual Tests	reference the job aid "Selecting a Serology Panel" and select the appropriate individual tests for your case and sample

Once all fields are filled, print the completed form. Click the "Reset Form" button if a second requisition needs to be completed. See attachment on last page for example of a completed form.

Using Accession Labels

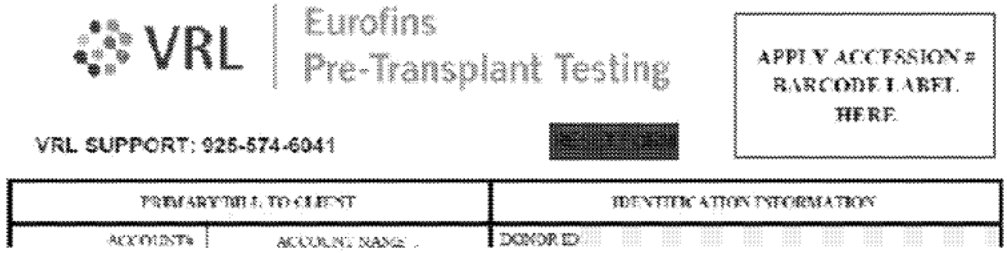
After labelling the blood tubes per policy, obtain a sheet of VRL accession labels.



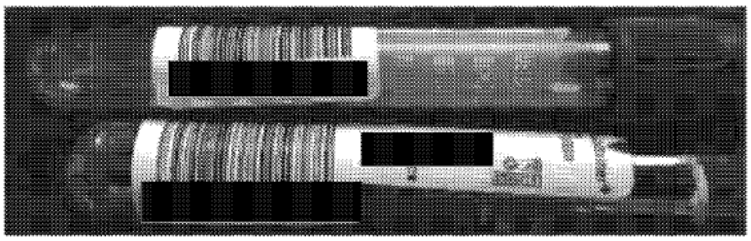
Updated 05.30.2019

DONORNETWORKWEST.org

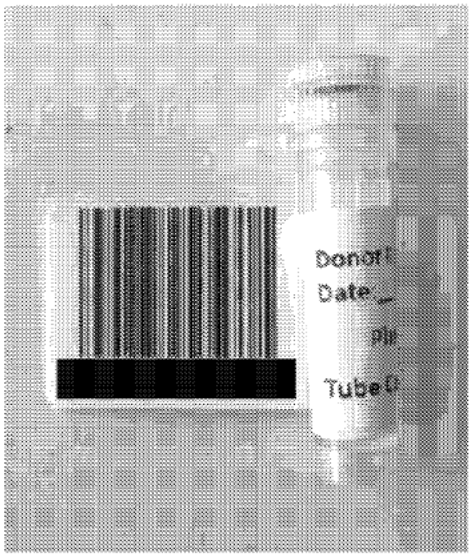
Place the accession barcode label that starts with "R" on the upper right corner of the printed requisition form.

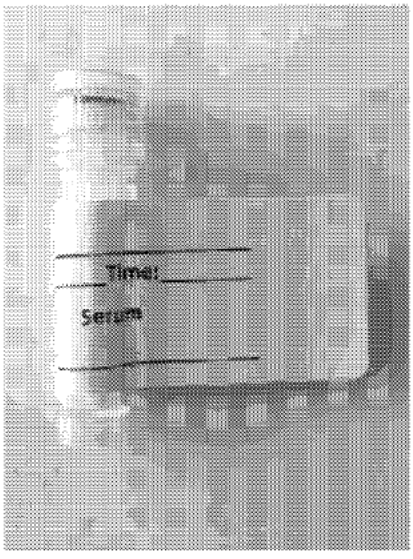


Place one accession barcode label that starts with "S" vertically on each blood tube. Vertical placement ensures easier scanning for VRL lab staff.



If blood is placed in an aliquot tube for testing, use the aliquot blood template and one accession barcode label that starts with "S". Combine these two stickers to wrap around the tube like so all information can be clearly seen and the accession barcode label can be easily scanned by VRL lab staff.





Updated 05.30.2019

DONORNETWORKWEST.org

Job Aid - Completing the VRL Tissue Donor Infectious Disease and ABO Testing Requisition

Example: Completed Tissue Donor Infectious Disease and ABO Testing Requisition

VRL | Eurofins Pre-Transplant Testing

VRL SUPPORT: 925-574-6041

[redacted]

APPLY ACCESSION # BARCODE LABEL HERE

PRIMARY/BILL TO CLIENT			IDENTIFICATION INFORMATION		
	ACCOUNT#	ACCOUNT NAME	DONOR ID [redacted]		
St	[redacted]	Donor Network West	DATE OF BIRTH [redacted]	AGE 33	GENDER F

SAMPLE INFORMATION

TEST RUN: ☒ ROUTINE

Please email Support@vrl-eurofins.com if samples will be submitted STAT

TOTAL # OF SAMPLES	4	TIME ZONE:	☐ EST ☐ CST ☐ MST ☒ PST ☐ Other_____	PACKAGED DATE/ TIME:	[redacted]	Shipper Type:	☒ Wet Ice ☐ Ambient ☐ None ☐ Other_____

SAMPLE INFORMATION	TRANSFUSION STATUS	COLLECTION DATE	COLLECTION TIME	CENTRIFUGE DATE	CENTRIFUGE TIME	REFRIGERATION DATE	REFRIGERATION TIME	FROZEN DATE	FROZEN TIME
☐ Pre-Mortem ☒ Post-Mortem ☐ Living	☒ Pre ☐ Post	[redacted]		[redacted]		[redacted]		N/A	N/A
☐ Pre-Mortem ☐ Post-Mortem ☐ Living	☐ Pre ☐ Post								
☐ Pre-Mortem ☐ Post-Mortem ☐ Living	☐ Pre ☐ Post								

PROFILE REQUESTED	REPORTS TO BE PROVIDED TO:
☐ 3348: Without BTLV: HBsAg, HBc Total, HCV, HIV 1&2, RPR, HIV/HCV/HBV NAT	☒ 1567 OptaLife ☐ 1360 LifeCell ☐ 1418 AlloSource ☐ 1526 LifeNet ☒ 1525 MTF ☐ 1695 Stanford ☐ 2341 CTS: Dayton Partners ☐ 2634 Aziyo Biologics, Inc. ☒ 1650 CorneaGen – Richmond
☒ 3469: With BTLV: HBsAg, HBc Total, HCV, HIV 1&2, HTLV I/II, RPR, HIV/HCV/HBV NAT	

INDIVIDUAL TESTS

☐ 0014: ABO/Rh	☐ 3012: HBc IgM	☐ 3004: CMV IgG	☐ 3214: HBsAg	☐ 3521: HIV 1&2	☐ 3548: HTLV I/II	☐ 3722: WNV NAT
☐ 3513: EBV IgG	☐ 3213: HBs Ab	☐ 3211: HBc Total	☐ 3221: HCV	☐ 3551: RPR	☐ 3588: Chagas	☐ 3770: HIV/HCV/HBV NAT

Donor Network West Coordinator Completing Form: _____

Tube A:_____ Tube B:_____ Tube C:_____ Tube D:_____ Tube E:_____ Tube F:_____ Other:_____

SE-F-012.01 Tissue Donor Infectious Disease and ABO Testing Requisition Effective: 04/15/2019

2240

Updated 05.30.2019

DONORNETWORKWEST.org

3.4 SE-F-019 ORGAN DONOR CULTURE TESTING REQUISITION (with Job Aid

DONOR NETWORK WEST

ORGAN DONOR CULTURE TESTING REQUISITION

BILLING INFORMATION	IDENTIFICATION INFORMATION
Donor Network West [redacted]	(DONOR ID LABEL)
SRRMC Clinic Code (assigned by ICP, if applicable) DL	
Physician Number: [redacted] - Donor Network, CA Transplant	
SRRMC Patient ID# (assigned by ICP, if applicable)	
Diagnosis: Potential Organ Donor	
ICD-10 Diagnosis for tests ordered: Code Z00.5 – Encounter for examination of potential of organ and tissue	REFERRAL ID: UNOS ID:

SPECIAL INSTRUCTIONS: ☒ STAT - Phone positive critical results to [redacted]

TOTAL # OF SAMPLES:

PACKAGED Date/Time: | PACKAGED BY:

SAMPLE INFORMATION	COLLECTION DATE	COLLECTION TIME	COLLECTION SITE/SOURCE
Blood Set #1 ☐ 87040			☐ Peripheral ☐ R arm ☐ L arm ☐ Central Line ☐ R IJ ☐ L IJ ☐ R SC ☐ L SC ☐ R groin ☐ L groin ☐ Arterial Line ☐ R arm ☐ L arm ☐ R groin ☐ L groin ☐ Other _____
Blood Set #2 ☐ 87040			☐ Peripheral ☐ R arm ☐ L arm ☐ Central Line ☐ R IJ ☐ L IJ ☐ R SC ☐ L SC ☐ R groin ☐ L groin ☐ Arterial Line ☐ R arm ☐ L arm ☐ R groin ☐ L groin ☐ Other _____
Urine ☐ 87086			☐ Foley catheter ☐ Other _____
Sputum Gram Stain ☐			☐ Bronch ☐ R ☐ L ☐ ETT
Sputum Culture ☐			☐ Bronch ☐ R ☐ L ☐ ETT
Sputum Culture ☐			☐ Bronch ☐ R ☐ L ☐ ETT
Other ☐			

SE-F-019.00 Organ Donor Culture Testing Requisition Effective: 12/18/19

2341 04.11.2019 (PT)

Completing the Organ Donor Culture Testing Requisition

About

The form SE-F-019, Organ Donor Culture Testing Requisition, is utilized for all culture specimens that are collected and sent to San Ramon Regional Medical Center for processing.

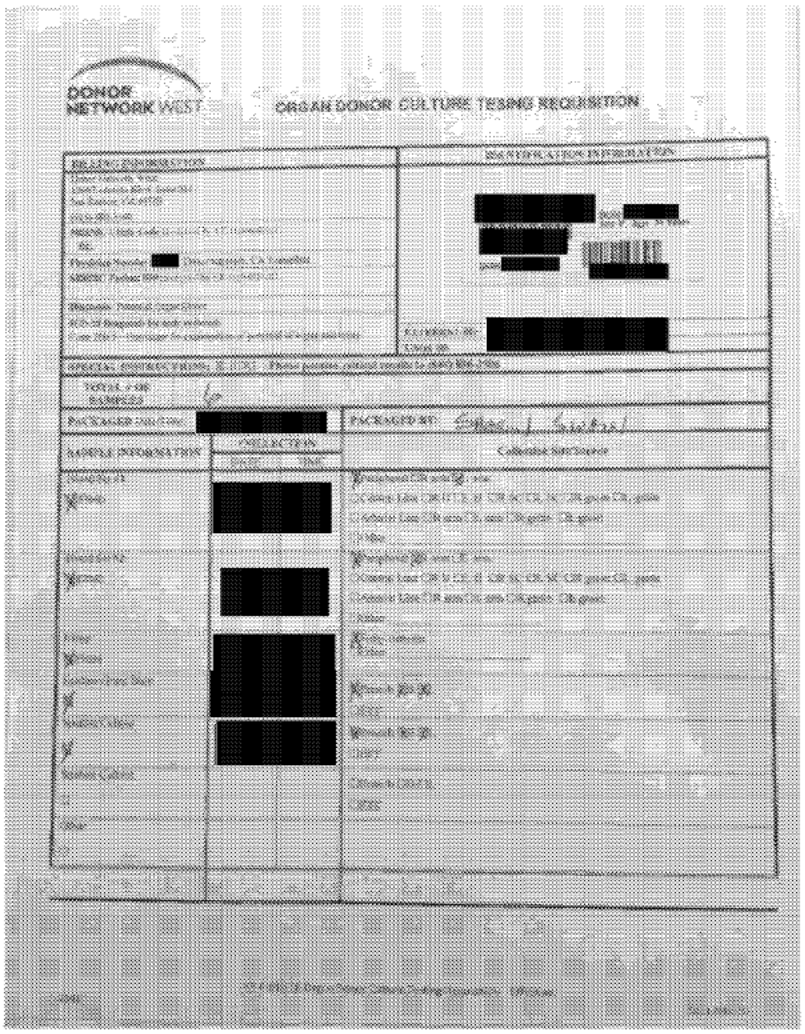
Completing the Form

Field	Information to enter
Donor ID Label	Place the donor ID label here (use the same label as the one on the specimen tubes).
Referral ID	Place the DNWest Referral ID number here. Note: this will allow for automatic upload to iTransplant.
UNOS Number	If available, place the UNOS number here.
Total # of Samples	Indicate the number of specimen containers being sent to SRRMC for culture testing.
Packaged Date/Time	Enter the date and time the specimens were packaged for shipment.
Packaged by	Enter your first and last name.
Sample Information	Select the appropriate test to be ordered. Note: each set of blood cultures must be drawn from different sites.
Collection Date	Enter the date the specimen was collected. Be sure it matches the date on the label adhered to the specimen container.
Collection Time	Enter the time the specimen was collected. Be sure it matches the time on the label adhered to the specimen container.
Collection Site/Source	Check the appropriate box for the site from which the specimen was collected.

Once all fields are completed scan a copy to attach to the electronic donor record. Enclose the original requisition per the culture kit instructions. .

Updated 11.13.19

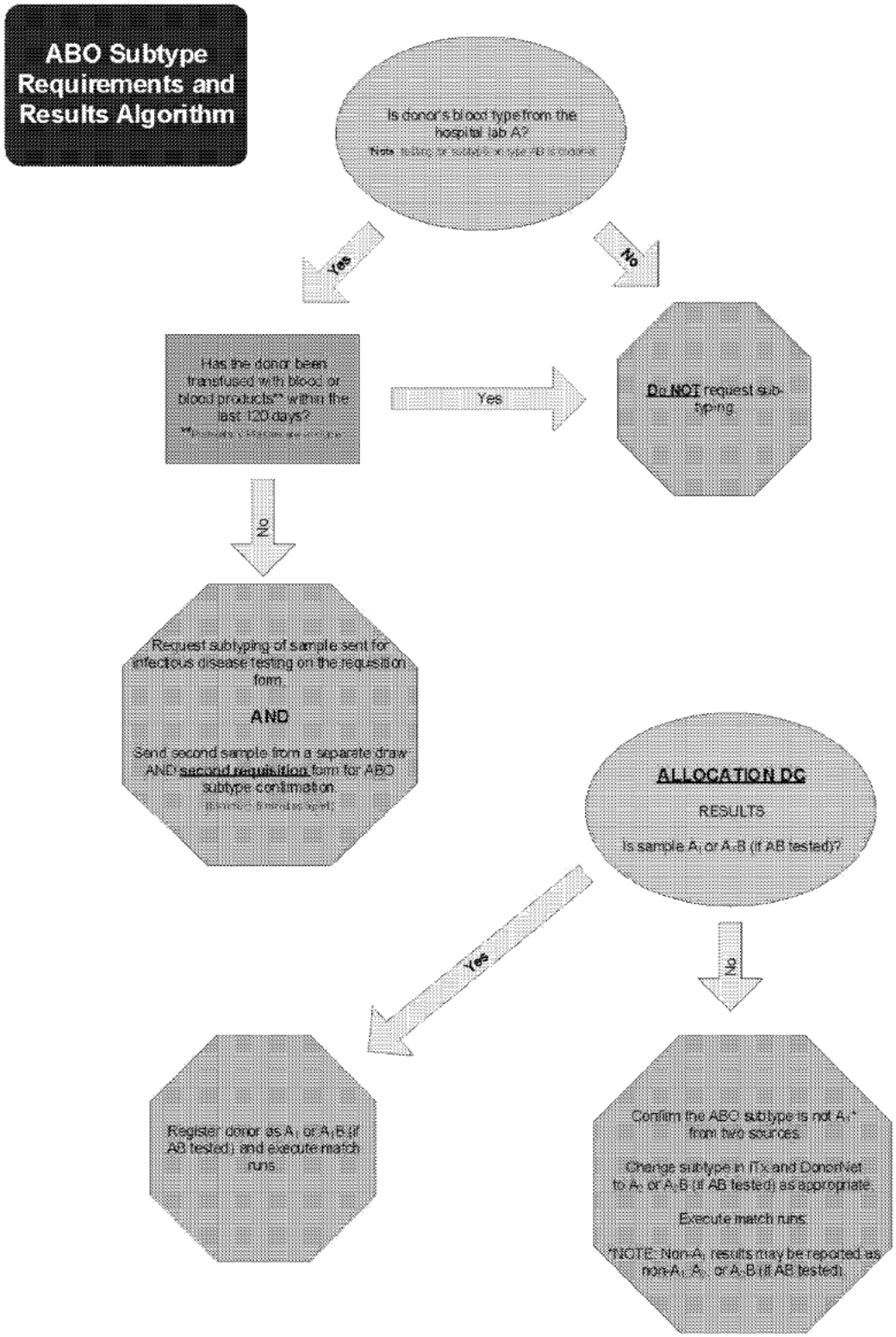
Example of completed Organ Donor Culture Requisition Form



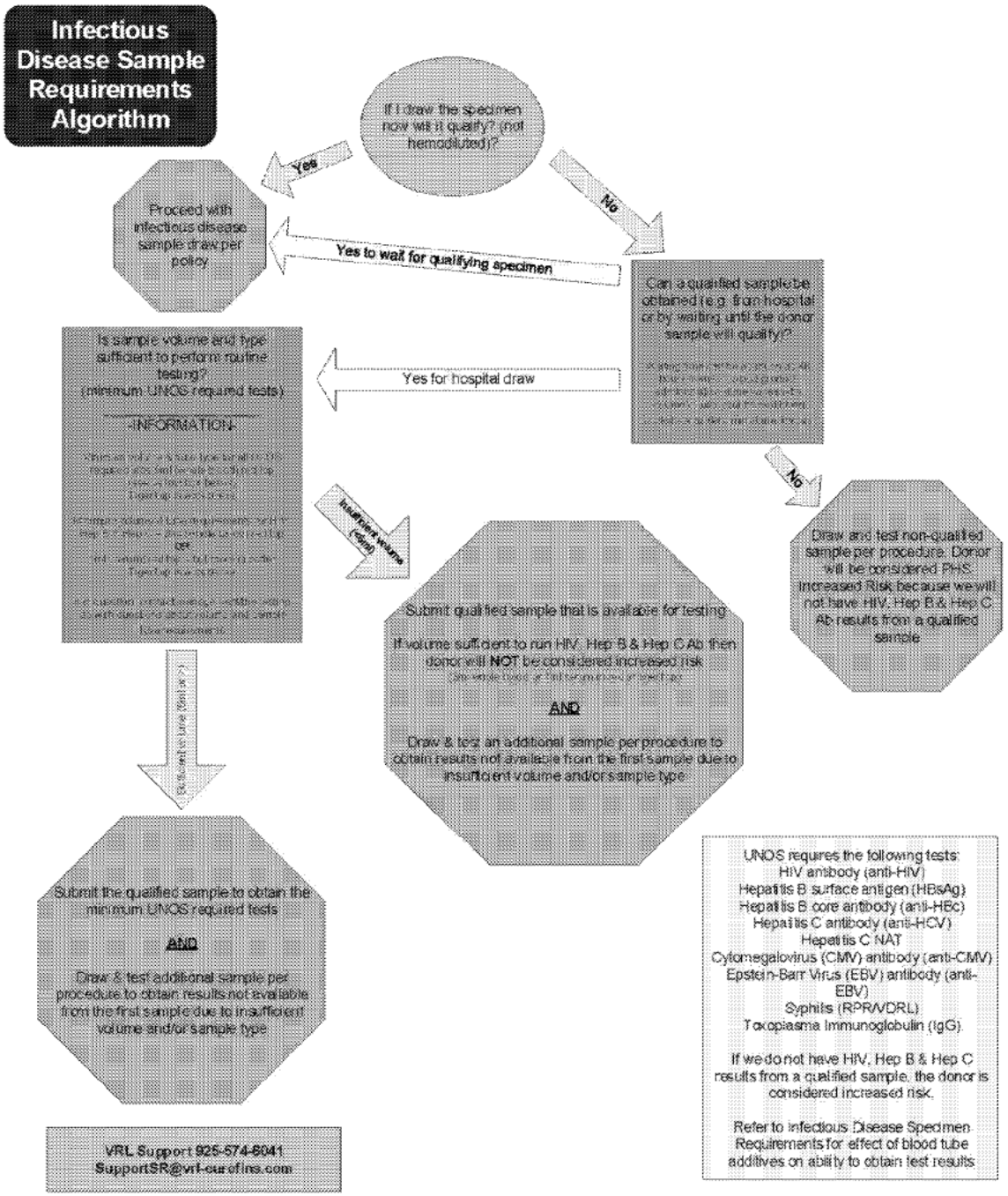
Updated 11.13.19

4.0 ATTACHMENTS

4.1 ABO SUBTYPE REQUIREMENTS AND RESULTS ALGORITHM



4.2 ORGAN ONLY: INFECTIOUS DISEASE SAMPLE REQUIREMENTS ALGORITHM

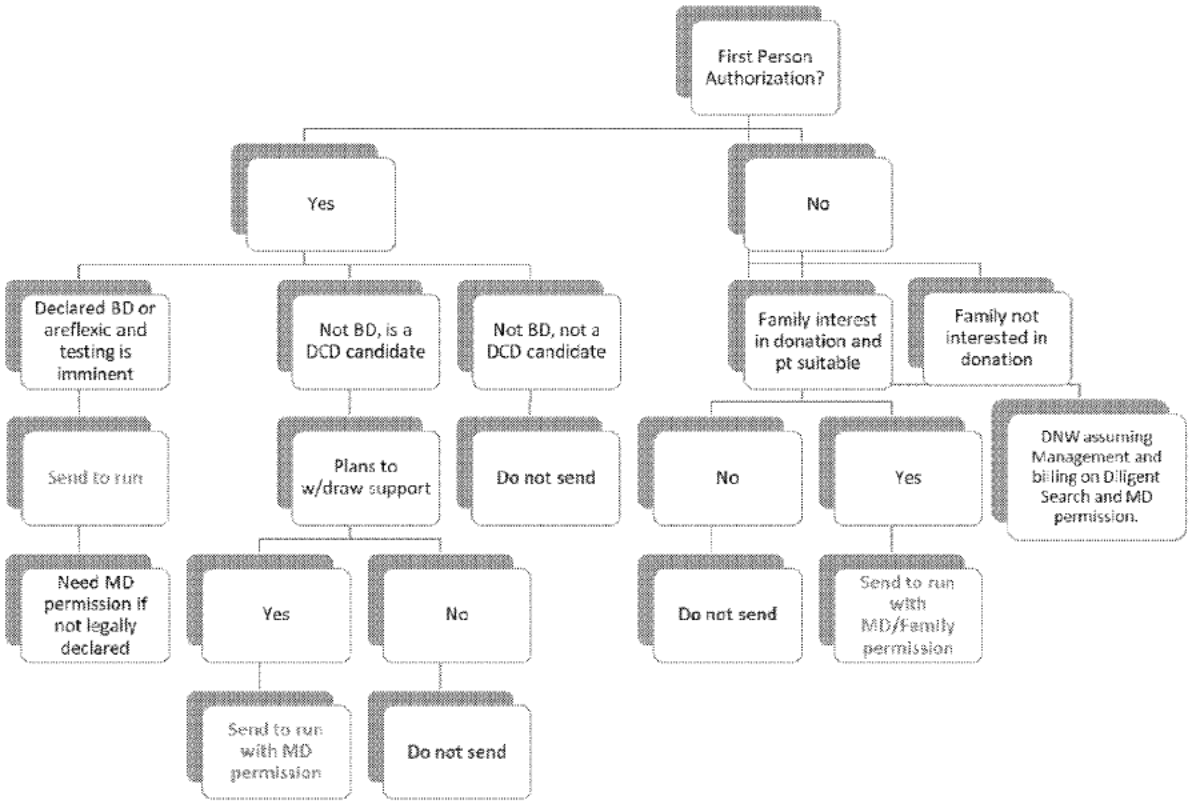


4.3 INFECTIOUS DISEASE CHECKLIST

UNOS/Donor ID#_____

- ☐ Hospital ABO w/hospital name attached to iTransplant and Allocation DC notified
- ☐ Hemodilution Status
  - ☐ All blood products entered since admission
  - ☐ Enter actual weight at time of calculation
    - ☐ Return to dry weight once calculation completed
  - ☐ Crystalloid administration one hour prior to draw
  - ☐ If specimen not qualified plan set with RTC/COM
- ☐ Blood tubes expiration dates confirmed (includes sub-type tube if applicable)
- ☐ Each blood tube label contains (includes sub-type specimen if applicable):
  - ☐ Full donor name (John Doe or Trauma designation ok) or initials
  - ☐ Date of birth
  - ☐ UNOS number or DNW unique identifier
  - ☐ Date/time of draw
- ☐ Requisition form
  - ☐ Label matches tube label
  - ☐ UNOS number or DNW unique identifier
  - ☐ Quantity of tubes
  - ☐ Date/time of draw matches date/time on label
  - ☐ HgbA1C if 10-55 years (if not performed at hospital)
  - ☐ nPod if research authorization and less than 30 years old
  - ☐ Supplemental testing requirements based on DRAI & addendum (Chagas, strongyloides)
  - ☐ Date/time in Shipper
  - ☐ Shipper Type (Wet Ice, Ambient, Nano)
    - ☐ Wet ice utilized for specimens to be tested > 6 hours after draw or specimens to be held for future testing
    - ☐ Ambient utilized for specimens to be tested < 6 hours after draw (DO NOT USE on specimens to hold)
  - ☐ NanoCool until supplies are exhaustedName of coordinator
- ☐ Sub-type - required if A (AB optional), over age 3 & no blood product in past 120 days (except plasma & platelets)
  - ☐ Draw specimen 5 minutes (minimum) apart from serology (or separate person draw)
  - ☐ Label requirements for tube met (name or initials, DOB, UNOS, date/time draw)
  - ☐ **Separate requisition with only ABO Subtype box checked** and all other identifiers present (labels match including date/time of draw, quantity, date/time in shipper, name of coordinator)
- ☐ Attach requisition(s) to electronic donor record
- ☐ Place requisitions in appropriate bag and place on top of styrafoam insert
- ☐ Packaged and courier notified
- ☐ Assigned to donor via BTM system

4.4 DONOR NETWORK WEST GUIDELINES: SENDING INFECTIOUS DISEASE TESTING PRIOR TO AUTHORIZATION



4.5 INFECTIOUS DISEASE TESTING TABLE

If sample for testing is limited, prioritize testing as indicated. If results of required testing indicate positive or reactive results, subsequent testing maybe automatically performed by the testing lab according to reflex agreement. Additional tests may be run and additional testing scenarios are possible. Test results are not 100% accurate and cannot be relied upon to definitively diagnose presence or absence of infection. Consult management / Chief Medical Officer as needed. All positive / reactive results, regardless of confirmatory / reflex testing and possible interpretations, MUST be communicated verbally to each accepting transplant center at the time of organ offer and included in donor highlights.

Testing Priority	Tests	Subsequent tests if required test are reactive	Reactive or Positive Results Indeterminate results are handled on a case-by-case basis but generally interpreted as reactive or positive			Comments
			Interpretation	DCs Notify COMs	DCs Notify Aftercare and QS	
1	**ABO & Rh**	None	Not applicable			If the donor is more than 3 years old, donor blood type is A (AB optional), and samples are pre-transfusion (transfusion of blood or blood products in the previous 120 days can affect results; however, plasma or platelets will not affect the determination of the A subtype), then subtyping should be performed. Type and subtype is required from samples drawn on two occasions. See ABO and Subgroup Testing and Verification procedure for more detail.
2	**Anti-HIV 1 & 2 Plus O**	Add HIV WB in cases of AB reactive / NAT neg.	If reactive, proceed as donor with confirmed exposure to human immunodeficiency virus.	**YES**	**YES**	Reactive results are interpreted to mean the donor's immune system has produced antibodies to the HIV 1 or HIV 2 virus. The window period from the time an individual is exposed to HIV and they produced antibodies at a detectable level is typically 3 to 4 weeks (may vary significantly). See 4.6 HIV Testing Interpretation Guidelines for additional information. If HIV Ab is reactive and HIV NAT is non-reactive or reactive non-discriminating, HIV Western Blot is run to estimate the accuracy of HIV Ab result. See 4.6 HIV Testing Interpretation Guidelines for HIV and 4.8 Hepatitis C Testing Interpretation Guidelines.
3	**HIV-1 / HCV NAT/ HBV NAT**		If reactive, defer to discriminatory testing.	**YES**	**YES**	The HIV-1, HCV, and HBV NAT tests are very sensitive and specific combined tests that replicate low concentrations of nucleic acids specific to HIV 1, HCV, and HBV to detectable concentrations. If reactive, a separate (discriminate) test for each virus is run to determine if nucleic acid from HIV-1, HCV, or HBV virus caused the reactive result.
		HIV NAT Discriminatory	If reactive, proceed as donor with confirmed exposure to human immunodeficiency virus.			A reactive result is interpreted to indicate nucleic acid from HIV-1 is present in the sample. The window period from the time of exposure to when the virus is detectable using this test is typically less than10 days, but can vary.
		HCV NAT Discriminatory	If reactive, additional testing and clinical information will determine if HCV infection is active. - If not active, proceed as standard donor. - If active, proceed as donor with confirmed exposure to hepatitis C.			A reactive result is interpreted to indicate nucleic acid from HCV is present in the sample. The window period from the time of exposure to when the virus is detectable using this test is typically around 10 days, but can vary. See 4.8 Hepatitis C Testing Interpretation Guidelines for additional information and use clinical information to determine if an active HCV infection is present.
		HBV NAT Discriminatory	If reactive, additional testing and clinical information will determine if HBV infection is active. - If not active, proceed as standard donor.			A reactive result is interpreted to indicate nucleic acid from HBV is present in the sample. The window period from the time of exposure to when the virus is detectable using this test is typically around 25 days, but can vary. See 4.7 Hepatitis B Testing Interpretation Guidelines for additional information and use clinical information to determine if an active HBV infection is present.

If sample for testing is limited, prioritize testing as indicated. If results of required testing indicate positive or reactive results, subsequent testing maybe automatically performed by the testing lab according to reflex agreement. Additional tests may be run and additional testing scenarios are possible. Test results are not 100% accurate and cannot be relied upon to definitively diagnose presence or absence of infection. Consult management / Chief Medical Officer as needed. All positive / reactive results, regardless of confirmatory / reflex testing and possible interpretations, MUST be communicated verbally to each accepting transplant center at the time of organ offer and included in donor highlights.

Testing Priority	Tests	Subsequent tests if required test are reactive	Reactive or Positive Results Indeterminate results are handled on a case-by-case basis but generally interpreted as reactive or positive			Comments
			Interpretation	DCs Notify COMs	DCs Notify Aftercare and OS	
			- If active, consult w/CMO			
		NAT reactive, non-discriminating	If NAT reactive, non-discriminating, this implies that the screening Ultrio detected one of the three viruses, yet the discriminating assays did not. This is often because the level of virus was too low for the discriminatory testing. We cannot assume that these three are negative, since the screening Ultrio is very sensitive and was positive.			The donor should be considered to potentially have all three infections. The Medical Director should be notified in the moment. The Lab should reflex to a HIV Western Blot, but only for future communications since it will not be back in time for allocation purposes. The donor can qualify as a HOPE donor. Pay close attention to antibody tests: • If HIV 1 and 2 Ab is reactive or non reactive, and HCV Ab, Hep B Core Antibody, and Hep B surface antigen are all non-reactive, the donor should be listed as a HOPE donor (HIV+), with HCV and HBV "indeterminate" on the box-check. The donor highlights must describe the donor as being NAT positive, non-discriminating; and all antibody testing results should be listed in donor highlights. • If the donor is Hepatitis B Surface antigen positive, we must list at HBV positive. • If the donor is Hepatitis C antibody positive, we must list as HCV positive. When a HOPE list is generated, the offers can be made via the HOPE list, but the OPO must disclose the "indeterminate" HCV and HBV status and document doing so. The HOPE Act's OPO Liaison can assist with outreach via the HOPE Act ListServ, which can serve as "calls of interest" to participating HOPE centers. The HOPE Act's OPO Liaison at 303-246-0647 can be very helpful to navigate in the moment.

Testing Priority	Tests	Subsequent tests if required test are reactive	Reactive or Positive Results Indeterminate results are handled on a case-by-case basis but generally interpreted as reactive or positive. Interpretation	DCs Notify COMs	DCs Notify Aftercare and QS	Comments
4	**HBsAg**		If reactive, additional testing and clinical information will determine if HBV infection is active. - If not active, proceed as standard donor. - If active, consult w/CMO.	**YES**	**YES**	Reactive results indicate a protein shed from the surface of the hepatitis B virus is present, suggesting HBV is in the sample. False reactives are possible. See 4.7 Hepatitis B Testing Interpretation Guidelines for additional information and use clinical information to determine if an active HBV infection is present.
		HBsAg Neutralization	Reactive (confirmed) result indicates an active hepatitis B infection. Consult w/CMO..			A non-reactive (not confirmed) HBsAg result is generally interpreted to mean proteins other than the hepatitis surface antigen protein caused the reactive HBsAg result, and the initial HBsAg test was not reactive due to antigens from HBV.
5	**Anti-HCV**	None	If reactive: - Proceed as donor with confirmed exposure to hepatitis C.	**YES**	**YES**	Reactive results are interpreted to mean the donor's immune system has produced antibodies to the hepatitis C virus. The window period from the time an individual is exposed to HCV and they produced antibodies at a detectable level is typically 2 to 3 months (may vary significantly). False reactives are possible. See 4.8 Hepatitis C Testing Interpretation Guideline for additional information and use clinical information to determine if an active HCV infection is present.
6	**Anti-HBC Ab**		If reactive, additional testing and clinical information will determine if HBV infection is active. - If not active, proceed as standard donor. - If active, consult w/CMO.	**YES**	**YES**	Reactive results are interpreted to mean the donor's immune system has produced antibodies to a protein from the core of the Hepatitis B virus. This is a test for hepatitis B core total (IgM and IgG). If reactive, subsequent testing helps determine if the patient has an active infection. False reactives are possible. See 4.7 Hepatitis B Testing interpretation Guidelines for further information.
		HBc IgM	Refer to Attachment 7.3 to determine if HBV infection is active. - If not active, proceed as standard donor. - If active, consult w/CMO.			A reactive result is interpreted to indicate the patient's body is producing IgM antibodies in response to an active infection. False reactives are possible. A non-reactive result is often interpreted to mean the initial Anti-HBC Ab (total) test detected HBc IgG (indicating a past infection). See 4.7 Hepatitis B Testing Interpretation Guidelines for further information.
		HBs Ab	Refer to Attachment 7.3 to determine if HBV infection is active. - If not active, proceed as standard donor. - If active, consult w/CMO.			A reactive result is interpreted to indicate the patient is producing antibodies to a hepatitis B surface antigen and the donor is not infectious. This marker is also present as a result of successful HBV vaccination. There are chronic carrier states where the immune system produces HBs Ab, but the patient remains infectious. False reactives are possible. See 4.7 Hepatitis B Testing interpretation Guidelines for further information.
7	**Syphilis Screening**		See *T. pallidum specific* when results of syphilis screening are reactive.			Non-reactive results are interpreted as non-reactive. Syphilis screening tests have high sensitivity but low specificity, meaning it is very effective at detecting infected samples, but readily produces false reactives. For this reason, reactive results defer to *T. pallidum specific* testing results for ultimate determination of syphilis infection status.
		Syphilis (*T. pallidum specific*)	Donation may proceed.	**YES**	**YES**	Reactive result suggests exposure to syphilis. Ensure treatment with PCN based antibiotics and proceed as standard donor. Non-reactive result is interpreted as non-infectious with a high degree of certainty (FDA allows final syphilis result to be reported as non reactive in this scenario).

Testing Priority	Required Tests	Subsequent tests if required test are reactive	Reactive or Positive Results Indeterminate results are handled on a case-by-case basis but generally interpreted as reactive or positive			Comments
			Interpretation	DCs Notify COMs	OCs Notify Aftercare and QS	
8	**CMV IgG Ab**	None	Donation may proceed.			Interpreted to indicate past infection.
9	**EBV IgG Ab**	None	Donation may proceed.			Interpreted to indicate past infection.
10	**WNV NAT**	None	Case-By-Case	**YES**	**YES**	Contact AOD and MD to determine if case should proceed.
11	**WNV Ab**	None	Case-By-Case	**YES**	**YES**	Contact AOD and MD to determine if case should proceed.
12	**Toxoplasma IgG**	None	Donation may proceed.	**YES**	**YES**	Anticipate that 20% of donor population will be positive. Not a contraindication for donation. Requires prophylactic treatment of the recipient.
13	**Chagas Screen (T. Cruzi Ab) *if* born in or resided in Latin America for >3 consecutive months.**	Chagas RIPA (requires 14 days)	Donation may proceed; however, heart transplant is not advised.	**YES**	**YES**	Chagas (T. Cruzi) testing is performed on donors considered to be at risk of infection. Risk is typically assessed via medical and social history screening and relates to time spent in Latin America (Mexico, Central, or South America). If a donor tests positive, donation may proceed; transplant centers must be made aware of the results so that recipients can be monitored closely and treated in the event of transmission. Chance of transmission is moderate dependant on the organ and level of immunosuppressant. Treatment has a high success rate.
14	**Strongyloides Ab (IgG)** **(if at risk for infection)**	None	Donation may proceed	**YES**	**YES**	Strongyloides testing is performed on donors considered to be at risk for infection. Risk is typically assessed via medical and social history screening and relates to time spent in endemic areas for greater than 3 months cumulatively (Appalacia*, Southeast United States**, Mexico, Puerto Rico, the Caribbean, Latin America, South America, Sub-Saharan Africa, Asia, India, and Oceania***). A person may be living outside of an endemic area for years or even decades and still be carrying the strongyloides parasite. Transplant centers receiving organ offers must be made aware of any testing in progress as turn around times for results may be longer than other tests. Transplant centers must be made aware of results so that recipeints can be treated prophylactically. *Southern NY, Pennsylvania, Southeast Ohio **Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee, Virginia, and West Virgina ***Australia and the group of islands in the South Pacific including Melanesia, Micronesia, Polynesia
15	**Coccidioides Ab, ID**	None	Donation may proceed; however, lung transplantation is not advised	**YES**	**YES**	Coccidioidodes (Valley Fever) testing is performed on all donors. Transplant centers receiving organ offers must be made aware of any testing in progress as turn around times for results may be longer than other tests. Transplant centers must be made aware of results so that recipients can be treated prophylactically.

4.6 HIV TESTING INTERPRETATION GUIDELINES

This table represents commonly anticipated scenarios based on standard testing protocols. Not all tests may be available and additional tests may be run and additional testing scenarios are possible. Test results are not 100% accurate and cannot be relied upon to definitively diagnose infection or absence of infection. Consult management / Chief Medical Officer as needed. Indeterminate results are interpreted on a case by case basis but are generally interpreted to mean reactive or positive. All positive / reactive results, regardless of confirmatory / reflex testing and possible interpretations, MUST be communicated verbally to each accepting transplant center at the time of organ offer and included in donor highlights.

Anti-HIV 1 and 2 plus O	HIV-1 and -2 NAT	Western Blot	Interpretation	Action[1]
-	-		Not Infectious for HIV	Proceed as standard donor
-	+		Likely infectious for HIV	Proceed as donor with confirmed exposure to Human Immunodeficiency Virus.
+	-	-	Likely false reactive Anti-HIV 1&2 and not infectious for HIV	If allocation has begun, close match runs and withdraw all pending organ offers or acceptances. Proceed as donor with confirmed exposure to Human Immunodeficiency Virus.
+	-	+	Possibly infectious for HIV	If allocation has begun, close match runs and withdraw all pending organ offers or acceptances. Proceed as donor with confirmed exposure to Human Immunodeficiency Virus.
+	+		Infectious for HIV	If allocation has begun, close match runs and withdraw all pending organ offers or acceptances. Proceed as donor with confirmed exposure to Human Immunodeficiency Virus.

4.7 HEPATITIS B TESTING INTERPRETATION GUIDELINES

This table represents commonly anticipated scenarios based on standard testing protocols. Not all tests may be available and additional tests may be run and additional testing scenarios are possible. Test results are not 100% accurate and cannot be relied upon to definitively diagnose infection or absence of infection. Consult management / Chief Medical Officer as needed. Indeterminate results are interpreted on a case by case basis but are generally interpreted to mean reactive or positive. All positive / reactive results, regardless of confirmatory / reflex testing and possible interpretations, MUST be communicated verbally to each accepting transplant center at the time of organ offer and included in donor highlights.

HBsAg	HBsAg Neutralization	Anti-HBc Ab	HBc IgM	HBs Ab	HBV NAT	Interpretation	Action*
-		-			-	Not Infectious for HBV.	Proceed as standard donor.
-		+	-	-	-	Most likely scenario is resolved HBV infection. Could also be false-positive anti-HBc.	Proceed on case-by-case basis (consult Chief Medical Officer).
-		+	-	-	+	Possible low level chronic infection, or resolving acute infection	Proceed on case-bycase basis (consult Chief Medical Officer).
-		+	-	+	-	Immune due to past exposure. Infectivity of liver transplants is approximately 50%. Infectivity of other organ groups is extremely low. Patient generally not considered infectious.	Proceed as standard donor.
-		-		+	-	Not Infectious for HBV. Immune due to hepatitis B vaccination.	Proceed as standard donor.
+	-					Suggests the initial HBsAg was a false reactive	Use interpretations in top four rows for non-reactive HBsAg scenarios.
+	-	+	-	-	-	Possible resolved HBV infection or false-positive anti-HBc.	Proceed on case-by-case basis (consult Chief Medical Officer).
-		+	+		-	May indicate recently cleared virus (no longer infectious).	Proceed on case-by-case basis (consult Chief Medical Officer).
+	-	+	-	-	+	Possible low level chronic infection or resolving acute infection.	Proceed on case-by-case basis (consult Chief Medical Officer).
+	+	+	-	-	+	Infectious for HBV. Chronic Infection.	Proceed on case-by-case basis (consult Chief Medical Officer).
+	+	+	+	-	+	Infectious for HBV. Acute Infection.	Proceed on case-by-case basis (consult Chief Medical Officer).

4.8 HEPATITIS C TESTING INTERPRETATION GUIDELINES

This table represents commonly anticipated scenarios based on standard testing protocols. Not all tests may be available and additional tests may be run and additional testing scenarios are possible. Test results are not 100% accurate and cannot be relied upon to definitively diagnose infection or absence of infection. Consult management / Chief Medical Officer as needed. Indeterminate results are interpreted on a case by case basis but are generally interpreted to mean reactive or positive. All positive / reactive results, regardless of confirmatory / reflex testing and possible interpretations, MUST be communicated verbally to each accepting transplant center at the time of organ offer and included in donor highlights.

Anti-HCV	HCV NAT	Interpretation	Action
-	-	Not Infectious for HCV	Proceed as standard donor.
-	+	Probably infectious for HCV. Likely infective for liver recipients, however infectivity rates by other organ types are variable (10-50%), related to active disease state.	Proceed as donor with confirmed exposure to hepatitis C. Other related information to determine ACTIVE infection, vs. prior exposure includes: current liver enzymes, liver biopsy (if available), any potential source(s) by history and current or past potential exposures (IVDA, incarcerations, etc.)
+	-	Possibly infectious for HCV. Likely infective for liver recipients, however infectivity rates by other organ types are variable (10-50%), related to active disease state.	Proceed as donor with confirmed exposure to hepatitis C. Other related information to determine ACTIVE infection, vs. prior exposure includes: current liver enzymes, liver biopsy (if available), any potential source(s) by history and current or past potential exposures (IVDA, incarcerations, etc.)
+	+	Infectious for HCV. Likely infective for liver recipients, however infectivity rates by other organ types are variable (10-50%), related to active disease state.	Proceed as donor with confirmed exposure to hepatitis C. Other related information to determine ACTIVE infection vs. prior exposure includes: current liver enzymes, liver biopsy (if available), any potential source(s) by history and current or past potential exposures (IVDA, incarcerations, etc.).

4.9 GUIDELINES FOR VERBALLY NOTIFYING PERSONAL REPRESENTATIVE OF REACTIVE INFECTIOUS DISEASE RESULTS

- "When we talked about the testing for donation during the authorization, we mentioned one of the items of concern would be any transmissible infection found in the blood tests run that are routinely obtained on all donors prior to recovery."
  - *If Donation Will Not Proceed Due To Reactive Infectious Disease*- "Our blood testing has turned up a result that will not allow (insert donor's name) to become a donor. This result now makes its necessary to call a halt to the donation because a potential infection could be passed onto any of the recipients or persons who had close contact with (donor's name). In this case (insert donor's name) was positive for (insert infectious disease name)." **NOTE: only an MD may disclose reactive HIV results.**
  - *If Donation Will Proceed With Reactive Infectious Disease*– "Blood testing has turned up a result that will still allow (insert donor's name) to become a donor, but shows a potential infection could be passed on to any of the recipient(s) or persons who had close contact with (donor's name)."
- "Our testing is as accurate and fast as current technology has to offer. The screening tests are very good; in fact, in an attempt to prevent disease transmission as much as possible, the tests are so sensitive in the short time available, they sometimes give a FALSE REACTIVE result."
- *If applicable:* "The reactive testing has two steps. We will automatically run the second step of this test to confirm the result. This step can take several days to get results."
  - "Considering all that is going to be happening between now and the time the second step testing is complete, we recommend you wait until that confirmatory result has come back. However, you are entitled to know the test result that stopped the donation."
  - "If the confirmatory result is the same as the first test result, there is the potential for persons who had close contact with (donor's name) to have been exposed to the infection."
- "The results can be made available to you at any time in the future and may be very important because of the potential for those in close contact with (donor's name) having been exposed to an infection."
- *If families indicate that they do not wish to be notified of a final confirmatory result, the coordinator must document that conversation in the Donor Network West Electronic Donor Record Narrative Notes with a copy and email or voicemail to the Manager of Donor Family Aftercare.*

Reactive Screening Test	Brief Description	Confirmatory Test	Turn Around Time	Disclosure to Personal Representative
Anti- HIV 1 & 2 Plus O combo	The HIV antibody test is a test for antibodies naturally produced in the body in the presence of the Human Immunodeficiency Virus, the virus that causes AIDS. The test, while highly accurate, does cause some falsely positive results. All samples that are first reactive are tested again using a more specific test.	HIV-1 Western Blot	7-10 days	Must be done by the donor's physician or CMO/Medical Director
HIV 1 / HCV / HBV NAT combo	The HCV, HIV, and HBV NAT (nucleic acid test) are tests for viral RNA and is made to be very sensitive in order to find the HIV 1, Hepatitis C, and Hepatitis B virus in infected people as early as possible. All combo samples that are first reactive are tested again using NAT tests specific for each virus to determine what virus caused the reactive.	HIV, HBV and HCV singlet (these are not confirmation tests)	6-8 hours	See reactive singlet testing below
HIV NAT Singlet	Performed when the HIV-1/HCV/HBV NAT combo is reactive	N/A	6-8 hours	Must be done by the donor's physician or CMO/Medical Director

Reactive Screening Test	Brief Description	Confirmatory Test	Turn Around Time	Disclosure to Personal Representative
HCV NAT Singlet	Performed when the HIV-1/HCV/HBV NAT combo is reactive	N/A	6-8 hours	Can be done by onsite coordinators in conjunction with the COM, CMO and/or Aftercare
HBV NAT Singlet	Performed when the HIV-1/HCV/HBV NAT combo is reactive	N/A	6-8 hours	Can be done by onsite coordinators in conjunction with the COM, CMO and/or Aftercare
HbsAg	The HbsAg tests for the presence of the Hepatitis B virus that can lead to liver disease. This first screening test reacted positively, but since this test can have false positive results, we automatically run a second confirmatory test.	HBsAg neutralization	4 hours	Can be done by onsite coordinators in conjunction with the COM, CMO and/or Aftercare
Anti-HBc	The Anti-HBc antibody test is a test for antibodies naturally produced in the body in the presence of the Hepatitis B virus, a virus that can lead to liver disease. Subsequent testing such as HBc IgM and HBsAb can indicate if an individual was presently able to spread the disease or if they were exposed in the past but not likely infectious.	Anti HBc IgM HBs Ab	4 hours	Can be done by onsite coordinators in conjunction with the COM, CMO and/or Aftercare
HCV	The Anti-HCV antibody test is a test for antibodies naturally produced in the body in the presence of the Hepatitis C virus. This virus can lead to liver disease. Not everyone who first tests positive for the Hepatitis C virus is truly infected with this virus. We automatically perform a second confirmatory test.	HCV RIBA 3.0	4-6 days	Can be done by onsite coordinators in conjunction with the COM, CMO and/or Aftercare
RPR	The RPR test is a screening test for the disease called syphilis, a treatable sexually transmitted disease. This screening test for syphilis is designed to be extremely sensitive, knowing that a few non-infected donors will show a false positive result. A second confirmatory test will automatically be run.	FTA-MHA/TPPA	4 hours	Can be done by onsite coordinators in conjunction with the COM, CMO and/or Aftercare

4.10 WORK INSTRUCTIONS – USE OF THE REACTIVE INFECTIOUS DISEASE NOTIFICATION LIST – PORTAL

Quality Systems will oversee the Reactive Infectious Disease Notification List -Portal.

New Entry

1. Enter a new notification completing the following elements:
    a. Brief Description
    b. Originator Name
    c. Entry Date
    d. Donor Name
    e. Referral I.D. Number
    f. Donor Network West Tissue Donor # (if applicable)
    g. UNOS ID # (if applicable)
2. Attach the following documents:
    - Infectious Disease Test Results
    - Applicable Authorization Form
    - Donor Medical and Social History Questionnaire(s)
3. Select "Save"
4. An email will alert Quality Systems and Aftercare that there is a new reactive infectious disease notification.

Quality Review and Notification

1. Upon receipt of the notification, Quality Systems review and determine the following:
    a. Complete all remaining elements in the Reactive Infectious Disease Notification list.
    b. Request missing information from the originator.
    c. Determine if the notification meets the reactive requirements. If the notification does not meet the requirements, Quality Systems will reject the notice and notify the originator.
    d. Reactive infectious disease tests will require the following notifications:
        i. Complete a State of California Confidential Morbidity Report and fax it to the county where the donor resides.
        ii. Contact the Chief Medical Officer to determine if family notification is recommended.
    e. If family notification is recommended, Quality Systems will assign a task to the Donor Network West Aftercare Team.

Donor Network West Aftercare Team Follow-up

1. Upon receipt of a new task, the Donor Network West Aftercare Team will review attached documentation and generate a letter to the family.
2. The portal list should be updated by completing the following elements:
    a. Family Notified by Phone?
    b. Date / Time of Phone Notification
    c. Family Notified in Writing?
    d. Date / Time of Written Notification
    e. Donor Network West Aftercare Team Comments (if applicable)
3. Select "Save".
4. An email will alert Quality Systems that the family follow-up is complete.

Review and Close Out

1. Quality Systems will review and close out the notification when all applicable information has been provided.
2. A copy of the notification will be saved and printed for the donor record.
3. Quality Systems will maintain an archive of all completed notifications.

Reflex Testing and Confirmation Testing

Reflex tests are ordered when a particular test result indicates that additional testing should be performed.

TISSUE TABLE

Test Description	Confirmatory/Reflex Test Description
HIV 1 & 2 + O	HIV 1 WB
HBsAg Reactive with HBV NAT Non-Reactive	HBsAg Neutralization
RPR	FTA-ABS

ORGAN TABLE

Test Description	Confirmatory/Reflex Test Description
HIV 1 & 2 + O	HIV 1 WB
HBsAg Reactive with HBV NAT Non-Reactive	HBsAg Neutralization
RPR	CAPTIA Syphilis IgG
RPR	RPR Titer
HBc Total Ab	HBc IgM

4.12 LIST OF COMMON BLOOD PRODUCTS, COLLOIDS, AND CRYSTALLOIDS

The following table lists examples of commonly administered blood or blood products, colloids, and crystalloids. If the actual amounts of product given are not available, the indicated volumes of blood, blood components, or colloids (as applicable) may be used to calculate the dilutional status of a specimen.

Red Blood Cells (PRBC, PC)	350 mLs per unit
Reconstituted Blood	
Whole Blood	500 mLs per unit
Colloids	**Volume**
Cryoprecipitate	10 mLs per unit
Dextran	500 mLs
Fresh Frozen Plasma	500 mLs per unit
Granulocytes	
Hespan/Hetastarch	500 mLs
Plasmanate	
Plasma Protein Fraction	
Platelet Concentrate	50 mLs per unit
5% Albumin	250 mLs or 500 mLs
25% Albumin *	70 mLs
Crystalloids	**Volume**
Cryoprecipitates Re-Suspended In Saline	
Dextrose/Water	
Isolyte	
Lactated Ringers	
Normal Saline	

Notes:

- Do not include auto-transfused blood, unless blood cells are returned to the donor after treatment with a cell saver.
- For 25% albumin, even if a lesser amount is documented, the minimum volume to be used in this calculation will be 70 mL.
- If neither units nor volumes are documented, but it is known that an ACLS protocol was initiated, a volume of 1000 mL will be used as the "worst case scenario" estimate of crystalloids infused.

5.0 RESOURCES

5.1 SPECIMEN GUIDE

Specimen Guide

Minimum Volume

This volume represents the minimum sample volume needed for a single test run. Repeat testing and confirmatory testing require additional volume. If you have questions concerning sample volume please call our Technical Support Group at 1-855-VRL-LABS.

VRL | Eurofins Pre-Transplant Testing

Test Name	*Minimum	Collection Tubes	Sample Stability
ABO/Rh Blood Typing *Micro Typing Systems*	50 µl cells 50 µl plasma	EDTA whole blood (lavender-top) Plain (red-top);	Within 14 days at 2-8°C. DO NOT FREEZE WHOLE BLOOD Within 5 days at 2-8°C. DO NOT FREEZE WHOLE BLOOD
Cytomegalovirus Total Antibody *Immucor-Capture*	50µl	EDTA plasma (lavender-top); Plain (red-top); NO SERUM SEPARATOR TUBE (speckled-top)	Plasma can be stored for 7 days at 1-10°C. Serum or plasma may be stored at –20°C.
Hepatitis B Virus Core Antigen *Ortho Clinical Diagnostics*	10 µl	Plain (red-top); Serum separator (speckled-top); EDTA plasma (lavender-top)	Within 7 days at 2-8°C. Frozen at –20°C for longer storage.
Hepatitis B Core IgM Antibody *Bio-Rad*	5 µl	Plain (red-top); Serum separator (speckled-top); EDTA plasma (lavender-top)	Specimens may be stored at 2-8°C for 48 hours. For long term storage, specimens should be frozen at –20°C.
Hepatitis B Surface Antigen *Bio-Rad*	100 µl	Living: Plain (red-top), Serum Separator (speckled-top); EDTA (lavender-top) Cadaveric: Plain (red-top), Serum separator (speckled-top)	Within 7 days at 2-8°C. Frozen at –20°C for longer storage.
Hepatitis B Surface Antigen Neutralization *Bio-Rad*	400 µl	Living: Plain (red-top), Serum Separator (speckled-top); EDTA (lavender-top) Cadaveric: Plain (red-top), Serum separator (speckled-top)	Within 7 days at 2-8°C. Frozen at ≤ –20°C for longer storage.
Hepatitis C Virus Antibody *Ortho Clinical Diagnostics*	15 µl	Plain (red-top); Serum Separator (speckled-top); EDTA (lavender-top)	Specimen may be stored at 2-8°C for 10 days or to 4 weeks at –20°C. DO NOT FREEZE WHOLE BLOOD.
Inno-LIA HCV Score *Innogenetics*	20 µl	Plain (red-top), Serum Separator (speckled-top); EDTA (lavender-top); Citrate (yellow); Heparin (green)	Within 7 days at 2-8°C. Freeze samples at –20°C or colder.
HIV-1/HIV-2 Plus O Antibody *Bio-Rad*	150 µl	Living: Plain (red-top), Serum Separator (speckled-top) or EDTA (lavender-top) Cadaveric: Plain (red-top), Serum separator (speckled-top)	Within 7 days at 2-8°C. For longer term storage, the specimen should be frozen at –20°C or colder.
HIV-1 Western Blot *Bio-Rad*	1000 µl	Plain (red-top); Serum Separator (speckled-top); EDTA (lavender-top)	Within 7 days at 2-8°C, or freeze at ≤ -20°C for longer term storage.

Specimen requirements can change. If you have any questions or concerns, please contact our Technical Support Group at 1-855-VRL-LABS.

Specimen Guide

Minimum Volume

This volume represents the minimum sample volume needed for a single test run. Repeat testing and confirmatory testing require additional volume. If you have questions concerning sample volume please call our Technical Support Group at 1-855-VRL-LABS.

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Test Name	*Minimum Volume	Collection Tubes	Sample Stability
Procleix® Ultrio® HIV-1/HCV/HBV NAT (TMA) *Gen-Probe*	500 µl	Living: EDTA plasma (lavender-top); Plain (red-top), Serum separator (speckled-top) Cadaveric: Plain (red-top), Serum separator (speckled-top), EDTA plasma (lavender-top)	Living Donor Specimens: Serum and Plasma may be stored for up to 72 hours from time of draw at 2-25°C; temperatures are not to exceed 30°C for more than 24 hours. Specimens may be stored for an additional 5 days at 2-8°C after centrifugation. Plasma separated from the cells may be stored for up to six (6) months at ≤-20°C. DO NOT FREEZE WHOLE BLOOD. Cadaveric Donor Specimens: (to include Pre-mortem non-heart-beating) 2-8°C for up to 72 hours, temperatures not to exceed 25°C for no more than 24 hours. Plasma; additional 5 days at 2-8°C after centrifugation. 14 days at ≤-70°C. Serum; additional 2 days at 2-8°C after centrifugation. 14 days at ≤-70°C
West Nile Virus NAT *Novartis*	500 µl	Living: EDTA plasma (lavender-top) Cadaveric: Plain (red-top), Serum separator (speckled-top), EDTA plasma (lavender-top)	Living Donor Specimens: Plasma may be stored for up to 72 hours from time of draw at 2-25°C; temperatures are not to exceed 30°C for more than 24 hours. Specimens may be stored for an additional 5 days at 2-8°C after centrifugation. Plasma separated from the cells may be stored for ≤9 months at ≤-20°C, or 15 months at –70°C. DO NOT FREEZE WHOLE BLOOD. Cadaveric Donor Specimens: 2-8°C for up to 72 hours, temperatures not to exceed 25°C for no more than 24 hours. Plasma (EDTA); additional 5 days at 2-8°C after centrifugation. Plasma separated from the cells may be stored for up to 11 days at ≤-70°C. Serum removed from the clot may be stored for up to 11 days at ≤-70°C.

Specimen requirements can change. If you have any questions or concerns, please contact our Technical Support Group at 1-855-VRL-LABS.

Specimen Guide

Minimum Volume

This volume represents the minimum sample volume needed for a single test run. Repeat testing and confirmatory testing require additional volume. If you have questions concerning sample volume please call our Technical Support Group at 1-855-VRL-LABS.

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Test Name	*Minimum Volume	Collection Tubes	Sample Stability
HTLV I/II Microelisa System *Axsym, Inc*	20 µl	Plain (red-top); Serum separator (speckled-top); EDTA plasma (lavender-top)	Within 14 days at 2-8°C. If over 14 days stored frozen at ≤ -20°C.
HTLV I/II Confirmatory *Innogenetics*	20 µl	Plain (red-top); Serum separator (speckled-top); EDTA plasma (lavender-top)	Serum or plasma should be separated from blood clot or cells by centrifugation. Store specimen at 2-8°C. For storage longer than 7 days, freeze at ≤-20°C.
Syphilis—RPR *Arlington Scientific*	50 µl	Plain (red-top); Serum separator (speckled-top); EDTA plasma (lavender-top)	Serum may be stored at 2-8°C for 5 days or at –20°C until testing. Plasma may by stored at 2-8°C for 5 days.
Captia™ Syphilis G Trinity Biotech	50 µl	Plain (red-top); Serum separator (speckled-top); EDTA plasma (lavender-top)	Serum may be stored at 2-8°C for 5 days or at –20°C until testing. Plasma may by stored at 2-8°C for 48 hours.

Specimen requirements can change. If you have any questions or concerns, please contact our Technical Support Group at 1-855-VRL-LABS.

Specimen Guide

Minimum Volume

This volume represents the minimum sample volume needed for a single test run. Repeat testing and confirmatory testing require additional volume. If you have questions concerning sample volume please call our Technical Support Group at 1-855-VRL-LABS.

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Cadaveric Profiles	*Minimum Volume	Collection Tubes	Sample Stability
Cadaveric Profile: HB core Total, HBsAg, HCV, HIV 1&2, HTLV I/II, RPR, HIV-1/HCV NAT	2ml of Serum and 640 µl of Plasma	Plain (red-top) or Serum separator (speckled-top) and EDTA Plasma (lavender-top)	See individual tests for stability requirements.
Cadaveric Profile: HB core Total, HBsAg, HCV, HIV 1&2, HTLV I/II, RPR, ABO/Rh, HIV-1/HCV NAT	50 µl of cells and 2 ml Serum and 700 µl of Plasma	Plain (red-top) or Serum separator (speckled-top) and EDTA Plasma (lavender-top)	See individual tests for stability requirements.
Cadaveric Profile: HB core Total, HBsAg, HCV, HIV 1&2, RPR, ABO/Rh, HIV-1/HCV NAT	50 µl of cells and 500 µl Serum and 500 µl Plasma	Plain (red-top) or Serum separator (speckled-top) and EDTA Plasma (lavender-top)	See individual tests for stability requirements.
Cadaveric Profile: HBsAg, HCV, HIV 1&2	300 µl	Plain (red-top) or Serum separator (speckled-top)	See individual tests for stability requirements.
Additional Assays	***Minimum Volume**	**Collection Tubes**	**Sample Stability**
Cytomegalovirus IgG EIA *Bio-Rad*	10 µl	Plain (red-top) or Serum separator (speckled-top)	Centrifuge as soon as possible and store serum at 2-8°C. May be stored for up to 7 days at –20°C.
Cytomegalovirus IgM EIA *Bio-Rad*	10 µl	Plain (red-top) or Serum separator (speckled-top)	Centrifuge as soon as possible and store serum at 2-8°C. May be stored for up to 7 days at –20°C.
EBV IgG/IgM EIA *Bio-Rad*	20 µl	Plain (red-top) or Serum separator (speckled-top)	Centrifuge as soon as possible and store serum at 2-8°C. May be stored for up to 7 days at –20°C.
Toxoplasma IgG EIA Bio-Rad	90 µl	Plain (red-top) or Serum separator (speckled-top)	Centrifuge as soon as possible. Samples not tested within 8 hours, should be stored at 2 to 8°C for up to 48 hours. Beyond 48 hours samples should be stored at –20°C or below.
Platelia™ TOXO IgM Bio-Rad	300 µl	Plain (red-top) or Serum separator (speckled-top) and EDTA Plasma (lavender-top)	Centrifuge as soon as possible. Samples can be stored at 2 to 8°C if testing is performed within 5 days, may be frozen at –20°C for several months.

Specimen requirements can change. If you have any questions or concerns, please contact our Technical Support Group at 1-855-VRL-LABS.

Specimen Guide

Minimum Volume

This volume represents the minimum sample volume needed for a single test run. Repeat testing and confirmatory testing require additional volume. If you have questions concerning sample volume please call our Technical Support Group at 1-855-VRL-LABS.

VRL | Eurofins Pre-Transplant Testing

Additional Assays	*Minimum Volume	Collection Tubes	Sample Stability
Strongyloides IgG ELISA *New Life Diagnostics*	500 µl	Plain (red-top) or Serum separator (speckled-top) and EDTA Plasma (lavender-top)	Centrifuge as soon as possible. Serum or plasma may be stored at 2 to 8°C for up to 5 days. Sample may be frozen –20°C or below for extended periods.
Trypanosoma cruzi ELISA Test System *Ortho*	3 ml	Living Donors, Plain (red-top) or Serum separator (speckled-top) and EDTA Plasma (lavender-top) Cadaveric Donors, Plain (red-top) or Serum separator (speckled-top) and EDTA Plasma (lavender-top)	Living Donors, Centrifuge as soon as possible. Samples may be stored up to 10 days for time of draw at 2 to 8°C following centrifugation, or up to 4 weeks at –20°C. Cadaveric Donors, Centrifuge as soon as possible. Samples may be stored up to 10 days for time of draw at 2 to 8°C following centrifugation, or up to 4 weeks at –20°C.
Reproductive Assays	***Minimum Volume**	**Collection Tubes**	**Sample Stability**
Chlamydia trachomatis *BD ProbeTec™ ET*		BD ProbeTec™ Urine Preservative Transport Kit	2-30°C for up to 30 days, store at –20°C for up to 60 days.
Neisseria Gonorrhea *BD ProbeTec™ ET*		BD ProbeTec™ Urine Preservative Transport Kit	2-30°C for up to 30 days, store at –20°C for up to 60 days.

Specimen requirements can change. If you have any questions or concerns, please contact our Technical Support Group at 1-855-VRL-LABS.

5.2 TUBE GUIDE

BD Vacutainer® Venous Blood Collection

Tube Guide

For the full array of BD Vacutainer® Blood Collection Tubes, visit www.bd.com/vacutainer.
Many are available in a variety of sizes and draw volumes (for pediatric applications). Refer to our website for full descriptions.

BD Vacutainer® Tubes with BD Hemogard™ Closure	BD Vacutainer® Tubes with Conventional Stopper	Additive	Inversions at Blood Collection*	Laboratory Use	Your Lab's Draw Volume/Remarks
Gold	Red/ Gray	• Clot activator and gel for serum separation	5	For serum determinations in chemistry. May be used for routine blood donor screening and diagnostic testing of serum for infectious disease.** Tube inversions ensure mixing of clot activator with blood. Blood clotting time: 30 minutes.	
Light Green	Green/ Gray	• Lithium heparin and gel for plasma separation	8	For plasma determinations in chemistry. Tube inversions ensure mixing of anticoagulant (heparin) with blood to prevent clotting.	
Red	Red	• Silicone coated (glass) • Clot activator, Silicone coated (plastic)	0 5	For serum determinations in chemistry. May be used for routine blood donor screening and diagnostic testing of serum for infectious disease.** Tube inversions ensure mixing of clot activator with blood. Blood clotting time: 60 minutes.	
Orange	Gray/ Yellow	• Thrombin	8	For stat serum determinations in chemistry. Tube inversions ensure mixing of clot activator (thrombin) with blood to activate clotting.	
Royal Blue		• Clot Activator (plastic serum) • K_2EDTA (plastic)	8 8	For trace-element, toxicology, and nutritional-chemistry determinations. Special stopper formulation provides low levels of trace-elements (see package insert). Tube inversions ensure mixing of either clot activator or anticoagulant (EDTA) with blood.	
Green	Green	• Sodium heparin • Lithium heparin	8 8	For plasma determinations in chemistry. Tube inversions ensure mixing of anticoagulant (heparin) with blood to prevent clotting.	
Gray	Gray	• Potassium oxalate/ sodium fluoride • Sodium fluoride/Na_2 EDTA • Sodium fluoride (serum tube)	8 8 8	For glucose determinations. Oxalate and EDTA anticoagulants will give plasma samples. Sodium fluoride is the antiglycolytic agent. Tube inversions ensure proper mixing of additive with blood.	
Tan		• K_2EDTA (plastic)	8	For lead determinations. This tube is certified to contain less than .01 µg/ml (ppm) lead. Tube inversions prevent clotting.	
	Yellow	• Sodium polyanethol sulfonate (SPS) • Acid citrate dextrose additives (ACD): **Solution A** - 22.0 g/L trisodium citrate, 8.0 g/L citric acid, 24.5 g/L dextrose **Solution B** - 13.2 g/L trisodium citrate, 4.8 g/L citric acid, 14.7 g/L dextrose	8 8 8	SPS for blood culture specimen collections in microbiology. ACD for use in blood bank studies, HLA phenotyping, and DNA and paternity testing. Tube inversions ensure mixing of anticoagulant with blood to prevent clotting.	
Lavender	Lavender	• Liquid K_3EDTA (glass) • Spray-coated K_2EDTA (plastic)	8 8	K_2EDTA and K_3EDTA for whole blood hematology determinations. K_2EDTA may be used for routine immunohematology testing and blood donor screening.*** Tube inversions ensure mixing of anticoagulant (EDTA) with blood to prevent clotting.	
White		• K_2EDTA with gel	8	For use in molecular diagnostic test methods (such as, but not limited to, polymerase chain reaction [PCR] and/or branched DNA [bDNA] amplification techniques.) Tube inversions ensure mixing of anticoagulant (EDTA) with blood to prevent clotting.	
Pink	Pink	• Spray-coated K_2EDTA (plastic)	8	For whole blood hematology determinations. May be used for routine immunohematology testing and blood donor screening.*** Designed with special cross-match label for patient information required by the AABB. Tube inversions prevent clotting.	
Light Blue Clear	Light Blue	• Buffered sodium citrate 0.105 M (=3.2%) glass 0.109 M (3.2%) plastic • Citrate, theophylline, adenosine, dipyridamole (CTAD)	3-4 3-4	For coagulation determinations. CTAD for selected platelet function assays and routine coagulation determination. Tube inversions ensure mixing of anticoagulant (citrate) to prevent clotting.	
Clear	Navy Red/ Light Gray	• None (plastic)	0	For use as a discard tube or secondary specimen tube.	

Note: BD Vacutainer® Tubes for pediatric and partial draw applications can be found on our website.

BD Diagnostics
Preanalytical Systems
1 Becton Drive
Franklin Lakes, NJ 07417 USA

BD Global Technical Services: 1.800.631.0174
vacutainer_tech_services@bd.com
BD Customer Service: 1.888.237.2762
www.bd.com/vacutainer

* Invert gently; do not shake.
** The performance characteristics of these tubes have not been established for infectious disease testing in general; the entity user must validate the use of these tubes for their specific assay/instrument/reagent system combinations and specimen storage conditions.
*** The performance characteristics of these tubes have not been established for immunohematology testing in general; therefore, users must validate the use of these tubes for their specific assay/instrument/reagent system combinations and specimen storage conditions.

Printed in USA 08/08 VS5229-8

5.3 TEMPLATE FOR BLOOD AND SPECIMEN LABELS

UNOS/DNWest ID#:
Donor Initials:
DOB: xx/xx/xxxx Date/time sample drawn:

Place accession barcode label here

UNOS/DNWest ID#:
Donor Initials:
DOB: xx/xx/xxxx Date/time sample drawn:

Place accession barcode label here

UNOS/DNWest ID#:
Donor Initials:
DOB: xx/xx/xxxx Date/time sample drawn

Place accession barcode label here

UNOS/DNWest ID#:
Donor Initials:
DOB: xx/xx/xxxx Date/time sample drawn:

Place accession barcode label here

UNOS/DNWest ID#:
Donor Initials:
DOB: xx/xx/xxxx Date/time sample drawn:

Place accession barcode label here

UNOS/DNWest ID#:
Donor Initials:
DOB: xx/xx/xxxx Date/time sample drawn

Place accession barcode label here

CORONER/ME LABELS

UNOS/DNWest ID #
Date of collection:
Time of collection:
Staff initials:
Collection site:
Specimen type: **BLOOD**

UNOS/DNWest ID #
Date of collection:
Time of collection:
Staff initials:
Collection site:
Specimen type: **BLOOD**

UNOS/DNWest ID #
Date of collection:
Time of collection:
Staff initials:
Collection site:
Specimen type: **BLOOD**

UNOS/DNWest ID #
Date of collection:
Time of collection:
Staff initials:
Collection site:
Specimen type: **BLOOD**

UNOS/DNWest ID #
Date of collection:
Time of collection:
Staff initials:
Collection site:
Specimen type: **BLOOD**

UNOS/DNWest ID #
Date of collection:
Time of collection:
Staff initials:
Collection site:
Specimen type: **BLOOD**

UNOS/DNWest ID #
Date of collection:
Time of collection:
Staff initials:
Collection site:
Specimen type: **BLOOD**

UNOS/DNWest ID #
Date of collection:
Time of collection:
Staff initials:
Collection site:
Specimen type: **BLOOD**

UNOS/DNWest ID #
Date of collection:
Time of collection:
Staff initials:
Collection site:
Specimen type: **BLOOD**

UNOS/DNWest ID #
Date of collection:
Time of collection:
Staff initials:
Collection site:
Specimen type: **URINE**

UNOS/DNWest ID #
Date of collection:
Time of collection:
Staff initials:
Collection site:
Specimen type: **URINE**

UNOS/DNWest ID #
Date of collection:
Time of collection:
Staff initials:
Collection site:
Specimen type: **URINE**

UNOS/DNWest ID #
Date of collection:
Time of collection:
Staff initials:
Collection site:
Specimen type: **VITRIOUS FLUID**

UNOS/DNWest ID #
Date of collection:
Time of collection:
Staff initials:
Collection site:
Specimen type: **VITRIOUS FLUID**

UNOS/DNWest ID #
Date of collection:
Time of collection:
Staff initials:
Collection site:
Specimen type: **VITRIOUS FLUID**

5.4 TEMPLATE FOR ALIQUOT BLOOD TUBE LABELS

Donor #:____________ Date:_______Time:_____ Plasma Serum Tube Color:____________	Donor #:____________ Date:_______Time:_____ Plasma Serum Tube Color:____________	Donor #:____________ Date:_______Time:_____ Plasma Serum Tube Color:____________
Donor #:____________ Date:_______Time:_____ Plasma Serum Tube Color:____________	Donor #:____________ Date:_______Time:_____ Plasma Serum Tube Color:____________	Donor #:____________ Date:_______Time:_____ Plasma Serum Tube Color:____________
Donor #:____________ Date:_______Time:_____ Plasma Serum Tube Color:____________	Donor #:____________ Date:_______Time:_____ Plasma Serum Tube Color:____________	Donor #:____________ Date:_______Time:_____ Plasma Serum Tube Color:____________
Donor #:____________ Date:_______Time:_____ Plasma Serum Tube Color:____________	Donor #:____________ Date:_______Time:_____ Plasma Serum Tube Color:____________	Donor #:____________ Date:_______Time:_____ Plasma Serum Tube Color:____________
Donor #:____________ Date:_______Time:_____ Plasma Serum Tube Color:____________	Donor #:____________ Date:_______Time:_____ Plasma Serum Tube Color:____________	Donor #:____________ Date:_______Time:_____ Plasma Serum Tube Color:____________
Donor #:____________ Date:_______Time:_____ Plasma Serum Tube Color:____________	Donor #:____________ Date:_______Time:_____ Plasma Serum Tube Color:____________	Donor #:____________ Date:_______Time:_____ Plasma Serum Tube Color:____________
Donor #:____________ Date:_______Time:_____ Plasma Serum Tube Color:____________	Donor #:____________ Date:_______Time:_____ Plasma Serum Tube Color:____________	Donor #:____________ Date:_______Time:_____ Plasma Serum Tube Color:____________
Donor #:____________ Date:_______Time:_____ Plasma Serum Tube Color:____________	Donor #:____________ Date:_______Time:_____ Plasma Serum Tube Color:____________	Donor #:____________ Date:_______Time:_____ Plasma Serum Tube Color:____________
Donor #:____________ Date:_______Time:_____ Plasma Serum Tube Color:____________	Donor #:____________ Date:_______Time:_____ Plasma Serum Tube Color:____________	Donor #:____________ Date:_______Time:_____ Plasma Serum Tube Color:____________

5.5 VRL WET ICE SHIPPER PACKING INSTRUCTIONS

(Also included in all shippers)

VRL | Eurofins Pre-Transplant Testing

Packing Instructions

No. 38936G

The enclosed specimen shipping system has been developed in accordance with the Exempt Human Specimen packaging requirements found in the IATA Dangerous Goods Regulations, Section 3.6.2.2.3.6.

2-8°C Wet Ice Shipper No. 38936G

Components:

VRL custom printed transport box
Small EPS foam cooler
Ambient gel wrap
6" x 7" foil bubble pouch
6" x 9" zip style biohazard bag
Aqui-Pak 4 tube absorbent pouch
12" x 12" absorbent sheet
10" x 10" x 4 mil plain zip style plastic bag with fill label
12" x 12" x 4 mil plain zip style plastic bag
Biohazard symbol label
12" x 12" bubble wrap sheet
2" x 24" adhesive tape strip (2)
Micro foam (use between December 1 and March 1)

Instructions for use:

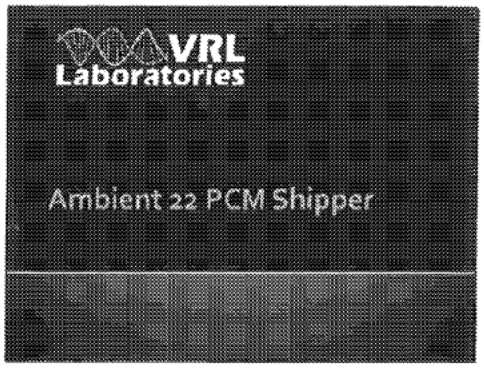
Once specimens are collected, open the kit transport box and remove all contents from the box. Follow the steps below to insure safe and compliant shipping:

1. Insert up to four sample tubes into the 4-bay Aqui-Pak absorbent pouch.
2. Roll the Aqui-Pak absorbent tube over tube, place into 6" x 9" biohazard bag, and seal the biohazard bag securely along the zippered track.
3. Place the biohazard bag and contents into the foil bubble pouch.
4. Remove the adhesive liner and seal the foil bubble pouch completely.
5. Place the foil bubble pouch and contents between the gel wrap.
6. Place the gel wrap with foil bubble pouch into the bottom of the small EPS foam cooler.
7. Insert micro foam – use this item between December 1 and March 1.
8. Fill the labeled 10" x 10" plain zip style plastic bag with 4 lbs. of crushed ice.
9. Seal the 10" x 10" plain zip style plastic bag with ice securely along the zippered track.
10. Place the 12" x 12" absorbent sheet into the 12" x 12" plain zip style plastic bag followed by the 10" x 10" plain zip style plastic bag with 4 lbs. of crushed ice.
11. Seal the 12" x 12" plain zip style plastic bag with crushed ice securely along the zippered track.
12. Place the 12" x 12" plain zip style plastic bag with crushed ice into the small EPS foam cooler, on top of the gel wrap and foil bubble pouch.
13. Fill the void space with the 12" x 12" bubble wrap sheet.
14. Replace the lid on the small EPS foam cooler. Attach the Biohazard symbol label to the outside of the foam box.
15. Complete patient requisition form and place on top of the small EPS foam cooler.
16. Attach completed airway bill to outside of box.
17. Seal the box closed using the included 2" x 12" adhesive tape strips.
18. Contact carrier for courier pick up.

38936G-V3-544886G

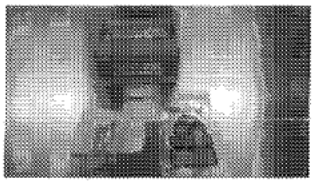
VRL | Eurofins Pre-Transplant Testing

VRL Ambient 22 PCM Shipper



Ambient 22 Shipper uses Phase Change Materials (PCM) to maintain a constant 22°C shipping temperature

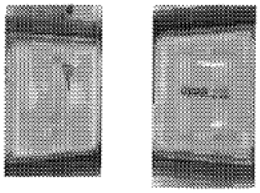
PCM 22 will constantly change from solid phase to liquid phase as internal temperatures heat or cool. This phase change allows internal shipping temp to maintain a constant 22°C shipping temperature.



No preconditioning of PCM is required. PCMs can be used in either solid or liquid phase.

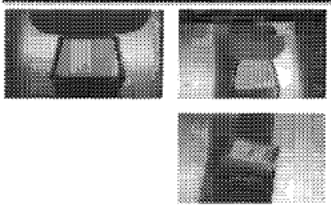
Packing Instructions

Components: (1) Aqui-pak 4 bay absorbent sleeve, (1) Biohazard leak proof bag, (1) Ambient 22 PCMs, (1) EPS VRL shipper.



1. Place labeled tubes in Aqui-pak absorbent sleeve. Place the Aqui-pak containing the tubes into biohazard bag. Use a separate Aqui-pak/ biohazard bag per donor.

2. Place biohazard bag on the bottom of the box. Place the Ambient 22 PCM on top of the biohazard bag. Pack up to 12 tubes.



3. Close Cooler lid. Place test request form on outside of lid.

4. Close tuck fold lid, and tape lid closed, add FedEx air bill to lid.

v7

TPX9 - 547503G

6.0 REFERENCES

6.1 AATB STANDARDS FOR TISSUE BANKING

§ D4.200 *Donor Testing*
§ D4.211 *Plasma Dilution*
§ D4.220 *Infectious Disease Testing*
§ D4.230 *Required Infectious Disease Tests*
§ D4.300 *Information Sharing*
§ F1.140 *Interpretation of Infectious Disease Test Results*

6.2 AOPO STANDARDS AND INTERPRETIVE GUIDELINES

CL 4D *Infectious Disease Testing*
CL6.6.1 *Verification of Donor ABO Type/Subtype if applicable*
SS 11 *Archiving Serum Tissue Samples*

6.3 CMS 42 CFR PARTS 413,441, ET AL. MEDICARE AND MEDICAID PROGRAMS; CONDITIONS FOR COVERAGE FOR ORGAN PROCUREMENT ORGANIZATIONS (OPO'S); FINAL RULE

§ 486.344 *Evaluation and Management of Potential Donors and Organ Placement and Recovery*
§ 486.344(d)(2)(i) *The OPO is responsible for two separate determinations of the donor's blood type*

6.4 FDA 21 CFR PART 1271 ELIGIBILITY DETERMINATION FOR DONORS OF HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE BASED PRODUCTS:

§ 1271.80 *What are the general requirements for donor testing?*
§ 1271.85 *What donor testing is required for different type of cells and tissues?*

6.5 UNOS

Policy 2.3: *Evaluating and Screening Potential Deceased Donors*
Policy 2.5: *Hemodilution Assessment*
Policy 2.6: *Deceased Donor Blood Type Determination and Reporting*
Policy 2.6.B: *Deceased Donor Blood Subtype Determination*
Policy 2.9: *Required Deceased Donor Infectious Disease Testing*
Policy 3.3: *Candidate Blood Type Determination and Reporting before Waiting List Registration*
Policy 5.3.B: *Infectious Disease Screening Criteria; Table 5-1 Donor Infectious Disease Screening Options*
OPTN Guidelines: *Guidance for ABO Subtyping Organ Donors for Blood Groups A and AB*

6.6 UAGA

Section 7150.65(c)

6.7 DONOR NETWORK WEST POLICY / DOCUMENTS

AL-P-001 DonorNet, Match Runs, and Allocation Documentation
AU-F-013 Authorization for Mother's Med Soc History and Testing
AU-P-003 Authorization for Anatomical Gift
DI-F-012 Notification of Significant Finding
EF-P-012 Equipment Operation, Cleaning, and Maintenance
OR-F-025 ABO Verification and OR Time Out Checklist
QS-P-002 Standard Documentation Practices
SE-F-016 Hemodilution Assessment
SE-F-017 Organ Donor Infectious Disease and ABO Testing Requisition
SE-F-018 Tissue Donor Infectious Disease and ABO Testing Requisition
TR-P-006 Collecting, Handling, and Shipping of Specimens

7.0 DEFINITIONS

ABO Blood Type – The classification of human blood into four groups: A, B, AB, and O.

ABO Subtyping – A serological testing process that is performed to identify ABO phenotypes (e.g. typing for the blood group). This applies to all donors who are ABO group A only (AB subtype is optional).

Acceptable Source – Sources used to identify and verify the donor ID and organ type (with laterality if applicable) including donor ID band, OPTN organ tracking system (UNet, TransNet), and OPTN-approved electronic methods.

Blood Cell Products – Any part of blood that includes cellular components.

Cardiac (Circulatory) Death – The cessation of blood flow through the cardiovascular system.

Colloid – A solution that contains natural or synthetic molecules that are relatively impermeable to the vascular membrane.

Confirmed Reactive — Affirmative testing results that establish the accuracy of a repeat reactive test scenario. A repeat reactive may represent a false result, so confirmatory testing uses alternate testing means to confirm or refute those results. [Note that confirmatory testing cannot overrule repeat reactive results with the exception of an FTA test used to confirm a syphilis agglutination test.]

Crystalloid – A solution that is essentially isotonic with human plasma and contains sodium as the primary osmotically active particle.

Indeterminate — This is a term commonly used to describe a test result that is so close to the test cut off that results are not able to be definitively determined. This may also be refered to as equivocal, gray zone, and / or inconclusive.

Infusion – Introduction of a crystalloid into the vein.

Non-Qualified (Sample) – A blood sample that, after assessment according to this procedure, has been diluted to a degree that could affect the results of infectious disease testing. Also referred to as "not qualified" or "unqualified".

Personal Representative – A person with legal authority to act on behalf of the decedent or the estate (not restricted to persons with authority to make health care decisions). Personal representative may be named in a Will. If no Will existed, the Personal Representative is typically named in the following priority: spouse, child or children, parent, sibling, niece or nephew. Note that Personal Representatives may be assigned to others (or in a different order) by the courts for legal reasons.

Plasma – Liquid portion of blood that remains when blood cells have been removed.

Plasmadilution – Dilution of donor plasma with blood, colloids, or crystalloids. Excessive plasmadilution can decrease the concentration of viral markers in a sample to a degree that makes them undetectable by infectious disease tests, even though a virus is present. Plasmadilution is also referred to as hemodilution.

Pre-mortem – samples obtained from donors with intact circulation

Post-mortem – samples obtained from donors where circulation has ceased

Qualified Health Care Professional (QHCP) – A person who is qualified to perform blood type reporting or verification requirements. Professionals include personnel from the organ program who are trained to perform these procedures.

Qualified (Sample) – A blood sample that, after assessment according to this procedure, has not been diluted to a degree that affects the results of infectious disease testing.

Repeat Reactive — Reactive results from duplicate tests that are performed if a sample tests reactive on the initial run. Generally, a single initial test is run. If it is non-reactive, the test result is reported as non-reactive. If it is reactive, the test is repeated in duplicate. If both repeat tests are non-reactive, the result is reported as non-reactive. If either or both tests are reactive, the test is reported as reactive or repeat reactive.

Serum – Liquid portion of blood remaining after blood cells and clotting factors (fibrinogen) have been removed.

Source Document – An original record of results (or a photocopy or digital copy of the original record) documenting the donor's blood type from the laboratory that performed the blood type testing.

The laboratory name must appear on the document on which the ABO is recorded.

Note: The form that has the hospital name already on it will be used, or the hospital name will be manually stamped onto the ABO page with the addressograph. If those options do not exist, the hospital name will be handwritten, and the entry will be dated and initialed as per STANDARD DOCUMENTATION PRACTICES.

Testing in Triplicate — A testing technique sometimes used to expedite testing of an organ donor's blood in which three tests are run at the same time. Organ procurement agencies interpret 0 or 1 reactive results as a net non-reactive result. Tissue banks must interpret 1 or more reactive results as net repeat reactive.

Transfusion – Introduction of blood, blood product, or colloid into the vein.

UAGA Section 7150.65(c) -When a hospital refers an individual at or near death to a procurement organization, the organization may conduct any reasonable examination necessary to ensure the medical suitability of a part that is, or could be, the subject of an anatomical gift for transplantation, therapy, research, or education from a donor or a prospective donor. During the examination period, measures necessary to ensure the medical suitability of the part may not be withdrawn, unless the hospital or procurement organization knows that the individual expressed a contrary intent.

Viable Leukocyte Rich Tissue – Tissues containing significant quantities of living white blood cells (that contain a nucleus and cytoplasm).

Attachment 9. Short Term Prevention

Attachment 10. Short Term Prevention

DNWest took the following short-term actions to prevent recurrence:

On 12-24-2020 communication was made to organ leadership:

[redacted] Thu 12/24/2020 12:40 PM

[redacted]

ABO Testing and Discrepant Results

To [redacted] Clinical Operations Manager; [redacted]

You replied to this message on 12/24/2020 12:47 PM.
This message was sent with High importance.

Team,

We have been in contact with UNOS regarding a recent ABO-related event and are taking the following immediate action while we assess the issue:

Effective immediately, any ABO test that indicates anything other than a conclusive result, or is in any way inconsistent with other ABO testing; must be reviewed by organ program clinical leadership including COM, AOD, and CMO.

Feel free to contact your AOD with any questions.

Please reply to acknowledge receipt.

[redacted]

[redacted]

DonorNetworkWest.org

As we gained understanding, the communication was enhanced and re-sent to organ leadership on 12-27-2020

[redacted] Sun 12/27/2020 10:30 AM
[redacted]
IMMEDIATE ABO Amendment--SE-M-001 Infectious Disease Testing Manual
To [redacted] Clinical Operations Manager; [redacted]

You replied to this message on 12/27/2020 10:33 AM.
This message was sent with High importance.

Infectious Disease Testing Manual.pdf
195 KB

Hello [redacted], AOD and COM teams.

The leadership team has been working through our occurrence in relation to ABO determination for UNOS [redacted] In response to UNOS, we are placing the below amendment into immediate action and I will be working on updating the Infectious Disease Testing Manual ASAP.

We have amended our previous instruction as follows: "All ABO tests must be considered when determining a donor's blood type. If any test indicates anything other than a conclusive result (including cancellation), or is in any way inconsistent with other ABO testing; all results must be reviewed by organ program clinical leadership and must follow SE-M-001, Section 2.2, Guidelines for Handling Conflicting Primary Blood Type Results. This includes testing by an outside (non-hospital) lab"

Please feel free to send follow up questions to your leadership.

[redacted]

DonorNetworkWest.org

The following communication was sent to the entire organ program, along with the Guidance Document, on 12-30-2020. The Guidance was also assigned in the learning management system.

Reply Reply All Forward

[redacted]
Wed 12/30/2020 6:41 AM

[redacted]

ABO/Blood Type Determination Guidance

To Clinical Operations Manager; Organ Allocation-PC; Clinical Procurement Coordinator; Clinical Procurement Coordinator Travelers; Clinical Procurement Coordinators; Regional Directors

Cc [redacted]

This message was sent with High importance.

Hello Team

We have recently experienced an occurrence, which has warranted a review of our policies and guidelines related to blood type determination. As our leadership team manages through enhancing our DNWest policy, we want to make sure you have additional information on the importance of accurately determining and reporting a donor patient's blood group. There are key terms within OPTN guidance to clarify:

- **Conflicting**: two blood tests from the same donor or candidate that show different blood types.
- **Indeterminate**: a blood test that does not provide a clear result.

All tests, whether complete or canceled must be considered. Any conflicting or indeterminate results must be elevated to the Administrator on Duty (AOD) and Chief Medical Officer (CMO) for further evaluation prior to organ offers.

For more information, we are providing the link to the OPTN Guidance of Blood Type Determination.

Any questions or concerns should be directed to your immediate supervisor, manager, director, or member of ELT.

[redacted]

[redacted]

DonorNetworkWest.org

Two mandatory ABO training sessions were held on 1-8-2020 for the organ program staff. A new ABO verification process was introduced.

Attachment 10. ABO and Subtype Testing and Verification

Procedure

DONOR NETWORK WEST

Title: ABO and Subtype Testing and Verification		
Document Number: **SE-P-011.00**	Page Number: **1 of 7**	Effective Date:

1.0 PURPOSE:

1.1 The purpose of this procedure is to describe the Donor Network West (DNWest) policy which mandates the determination of two separate blood group determinations on all potential organ donors in compliance with UNOS/OPTN policy.

Commented [A1]: We do not have track changes available because this is a new procedure. It had been a section of a larger infectious disease testing manual; and is now pulled out as a stand-alone document to create greater visibility and narrower scope. We have attempted to indicate relevant changes as comments.

2.0 SCOPE:

2.1 This procedure applies to all potential organ donors.

3.0 RESPONSIBILITIES:

3.1 Qualified Health Care Professionals (QHCP) - Organ Program staff responsibility to:

3.1.1 Obtain two separate ABO and subtype (if applicable) determinations.

3.1.2 Use all source documents to determine donor blood type and subtype (if applicable).

3.1.3 Enter and verify the donor's blood type and subtype (if applicable) in the Donor Network West Electronic Donor Record (DONOR RECORD) and DONORNET.

3.1.4 Make all blood type documentation and transfusion history available in DONOR RECORD and DONORNET.

Commented [A2]: This was not indicated in previous ABO procedure

4.0 REFERENCES:

4.1 AOPO Standards

4.1.1 CL6.6.1 *Verification of Donor ABO Type/Subtype if applicable*

4.2 CMS 42 CFR Parts 413, 441, 486 and 498: Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations (OPOs)

4.2.1 § 486.344(d)(2)(i) The OPO is responsible for two separate determinations of the donor's blood type.

4.3 UNOS Standard

4.3.1 Policy 2.5

4.3.2 Policy 2.6A.: *Deceased Donor Blood Type Determination*

4.3.3 Policy 2.6.B: *Deceased Donor Blood Subtype Determination*

4.3.4 Policy 3.3.: *Candidate Blood Type Determination and Reporting before Waiting List Registration*

4.3.5 OPTN Guidelines: *Guidance for ABO Subtyping Organ Donors for Blood Groups A and AB*

4.4 Donor Network West Policy

4.4.1 QS-P-002 STANDARD DOCUMENTATION PRACTICES

4.4.2 AL-P-001 DONORNET, MATCH RUNS, AND ALLOCATION DOCUMENTATION

4.4.3 SE-P-008 ORGAN INFECTIOUS DISEASE TESTING AND NOTIFICATION OF RESULTS

5.0 DEFINITIONS:

5.1 *ABO Blood Type* – The classification of human blood into four groups: A, B, AB, and O.

5.2 *ABO Subtyping* – A serological testing process that is performed to identify ABO phenotypes (e.g. typing for the blood group). This applies to all donors who are ABO group A only (AB subtype is optional).

5.3 *Conflicting* – Two blood tests from the same donor or candidate that present with different blood typing results.

5.4 *Indeterminate* – A blood test that does not provide a clear result. Examples include: indeterminate, cancelled, invalid, inconclusive, equivocal, pending, etc.

Commented [A3]: New definition added for indeterminate

5.5 *Protocol* – A predefined written procedural method.

5.6 *Qualified Health Care Professional (QHCP)* – A person who is qualified to perform blood type reporting or verification requirements. Professionals include personnel from the organ program who are trained to perform these procedures.

5.7 *Source Document* – An original record of the test results (or a photocopy or digital copy of the original record) documenting the donor's blood type from the laboratory that performed the blood type testing.

5.7.1 The laboratory name must appear on the document on which the ABO is recorded.

Note: The source document with the hospital name already on it will be used, or the hospital name will be manually stamped onto the ABO page. If those options do not exist, the hospital name will be handwritten, and the entry will be dated and initialed as per STANDARD DOCUMENTATION PRACTICES.

6.0 DOCUMENTATION / FORMS:

6.1 OR-F-025 ABO VERIFICATION AND OR TIME OUT CHECKLIST

6.2 OPTN Organ Tracking System (TransNet, DONORNET)

7.0 ATTACHMENTS:

7.1 ABO Subtype Requirements and Results Algorithm

8.0 MATERIALS / SUPPLIES:

8.1 None.

9.0 PROCEDURE:

9.1 BLOOD COLLECTION

Refer to SE-P-008 ORGAN INFECTIOUS DISEASE TESTING AND NOTIFICATION OF RESULTS for instructions on collecting and submitting blood to VRL for ABO and infectious disease testing.

The DNWest on-site coordinator shall be responsible for obtaining two separate ABO determinations, and subtype if indicated, that meet the following requirements:

9.1.1 Two separate samples for ABO and subtyping (if used for allocation) must:

- Be taken on two separate occasions,
- Have different collection times (at least 5 minutes must elapse between draws);
- Be submitted as separate samples.

9.1.2 One of the samples must be tested by a non-hospital lab (i.e. infectious disease testing lab).

9.1.3 If the patient has received transfusions with type O blood at any time associated with the current hospitalization (e.g. by paramedics, at a hospital or emergency department prior to the current hospital, etc.), one of the ABO results must be performed on pre-transfusion blood. If no pre-transfusion blood is available, testing for blood type genotyping using molecular methods (e.g. PCR) shall be used.

9.1.4 Subtyping is required when the following three conditions are met:

- The donor is more than 3 years old;
- The donor's ABO blood type is A (AB is optional); and
- Both subtype determinations can be made on pre-transfusion samples (transfusion of blood or blood products in the previous 120 days can affect results; however, plasma or platelets will not affect the determination of the A subtype).
- For all blood type A donors, document either that subtyping was completed or the reason it could not be completed in the Donor Record .

9.1.5 Attach ALL ABO testing source documents (including indeterminate) in the DONOR RECORD and in DonorNet.

9.2 BLOOD TYPE DETERMINATION

Blood type determinations must be made as follows:

9.2.1 All known available blood test type and subtype determinations must be finalized. Source documents must be obtained and all tests must be used to verify that they:

- Contain blood type and subtype (if used for allocation) results for the donor.
- Indicate the same blood type and subtype (if used in allocation) on the test results. If results are conflicting or indeterminate, refer to OPTN Guidance for ABO Subtyping Organ Donors for Blood Groups A and AB and follow instructions in Section 9.5.

9.2.2 Two qualified health care professionals (QHCP), one of which must be a Clinical Operations Manager (COM), will make an independent determination of blood type. Both QHCPs must enter and verify blood type determination in the DONOR RECORD .

Commented [A4]: These requirements were in one sentence in our previous procedure but are now bulleted out for clarity.

Commented [A5]: This is a new requirement

Commented [A6]: This new requirement is proposed and dependant on further research regarding availability of testing / logistical issues.

Commented [A7]: This is a new requirement to this procedure. It was previously practice.

Commented [A8]: The previous policy indicated: If a discrepancy exists between the source documents, an additional sample for ABO determination will be obtained and tested at the donor hospital, or other designated testing site, in an attempt to resolve the discrepancy. It also indicated referring to our Guidelins for Handling Conflicting Primary Blood Type Results.

Commented [A9]: Previous procedure did not required a higher level (COM) review.

9.2.3 ABO verification status will be discussed in the Pre-Allocation Huddle to assure:

- All transfusion history is accounted for
- All tests have been finalized and obtained
- One test is from a non-hospital lab
- Either one result is from a sample collected before transfusion with Type O blood, or testing for blood type genotyping using molecular methods (e.g. PCR) was performed

9.2.4 Upon completion of DNWest Pre-Allocation Huddle (PAH), two different QHCPs must enter and verify blood type determination in DonorNet Donor Summary.

9.2.5 The deceased donor is not eligible for a match run until the host OPO completes the above blood type determination and verification.

9.2.6 If this verification process cannot be completed due to an expedited donor process, it may be completed after the match run, but prior to organ release in order to avoid organ waste. Document the following in a progress note in the electronic donor record:

- The reason that both blood type tests (and subtype tests, if used for allocation) could not be completed, verified, and reported prior to the match run;
- If there are conflicting or indeterminate primary blood type test results, refer to section 9.5 to address the discrepancy and re-execute the match run if the final ABO result is different from the initial ABO on the original match run.
- That all required blood type and subtype requirements, determinations, verification, and reporting were completed prior to organ release to a transplant hospital

Commented [A10]: Previous procedure did not indicate use of an ABO checklist in the Pre-Allocation Huddle for use after initial verification in iTransplant.

Commented [A11]: Previous procedure did not delineate a 3 step process (1. Verification in our Electronic Donor Record, 2. Review using a checklist in Pre-Allocation Huddle, 3. Verification in DonorNet).

Commented [A12]: Previous procedure did not induce a process for expedited donors.

9.3 ALLOCATION

9.3.1 Allocation of organs will be based on the donor's primary blood type without consideration of subtyping in the following instances:

- Pretransfusion specimens are not available;
- The laboratory is unable to interpret results;
- Subtyping results are conflicting or indeterminate:
- Allocation has begun prior to subtype results being confirmed.

9.4 RECOVERY BLOOD TYPE DOCUMENTATION AND REPORTING

9.4.1 Upon recovery team arrival and prior to incision, the on-site coordinator, who is a QHCP, will review the entire donor record and will verify the donor ID, ABO and subtype (if applicable), and organs to be recovered (including laterality) using source documents and acceptable sources, with each lead recovery surgeon/personnel.

9.4.2 The verification of ABO and OR Time Out Checklist will be signed by the on-site coordinator and each lead recovery surgeon/personnel.

9.4.3 A copy of page one of the signed Verification of ABO and OR Time Out Checklist form with the ABO Verification section completed will be:

- Included in the donor record that accompanies each organ;
- Attached to the Donor Record; and
- Attached in DonorNet.

9.5 CONFLICTING OR INDETERMINATE PRIMARY BLOOD TYPE RESULTS

The purpose is to ensure recipient safety by establishing a consistent method for addressing and resolving conflicting or indeterminate primary blood type results. Examples include: indeterminate, cancelled, invalid, inconclusive, etc.

Factors impacting blood typing reliability may include, but are not limited to: transfusion, ABO non-identical stem cell transplant, infections and cancers, elevated globulin levels, A-weak, B-weak, and blood type subgroups, immunosuppression, and age (under 6 month). (See OPTN Guidelines: *Guidance for ABO Subtyping Organ Donors for Blood Groups A and AB)*

Should a conflicting or indeterminate ABO test occur, the following steps should be taken:

9.5.1 Initiate a HARD STOP. The CMO should be contacted immediately to guide the process of determining blood type, including contacting the Blood Banks and Reference labs and UNOS to get the information required to determine the course of action.

9.5.2 If offers have been made, DNWest CMO will communicate circumstances to affected surgeons.

9.5.3 For policy guidance regarding ABO determination, the CMO will initiate communication with UNOS.

9.5.4 A primary blood type, from current event, conducted prior to any transfusion should be used as the standard for matching.

9.5.5 Contact all blood banks and infectious disease testing lab associated with the donors current admission course starting with the originating hospital and confirm ABO testing and transfusions received. Consider pre-hospital administration of blood products.

9.5.6 His[redacted]al blood type results for reference.

9.5.7 Initiate a huddle with the OAC, CPC, COM, CMO, and AOD to establish a plan and document in DONOR RECORD. Blood banking physicians and scientific experts should be consulted as needed to review the entirety of the circumstances. Potential actions may include additional or alternate testing. Such circumstances may include:

- Massive transfusion without a pretransfusion sample.
- Result comments suggesting a different underlying type.
- Discrepancies between forward (antigen) and reverse (antibody) typing.
- [redacted] reporting invalid or inconsistent testing.

9.5.8 When efforts to resolve the discrepancy have been exhausted, the following match run sequence should take place with the more restrictive blood type to be utilized for the match run. A pre-transfusion specimen should be used as the standard for the match run. Situations in which this would occur include blood transfusions administered via massive transfusion protocol prior to, and/or in between, blood draws.

- A blood type and O blood type = match run on A blood type.
- B blood type and O blood type = match run on B blood type.
- A blood type and B blood type = match run on AB blood type.
- A blood type and AB blood type = match run on AB blood type.
- B blood type and AB blood type = match run on AB blood type.
- O blood type and AB blood type = match run on AB blood type.

Commented [A13]: Factors and reference to Guidance were not part of the previous policy.

Commented [A14]: Emphasize CMO involvement from the beginning

Commented [A15]: Added instructions to verify all testing and transfusion information.

Commented [A16]: New procedure indicates historical samples may be used as reference

Commented [A17]: Huddle now called for purposes of resolving the discrepancy. Indicates consult with experts. Was previously indicated when discrepancies could not be resolved.

- Should the A subtype be in conflict, then the donor will be considered to be A1 or A1B as appropriate.

9.5.9 When donor blood typing results remain in conflict and unable to be resolved, the safest course of action is to consider the donor to be blood type AB to ensure that only AB blood type candidates, as universally ABO compatible recipients, would be considered to receive the organs from that donor.

9.5.10 Document and communicate the circumstances as follows:

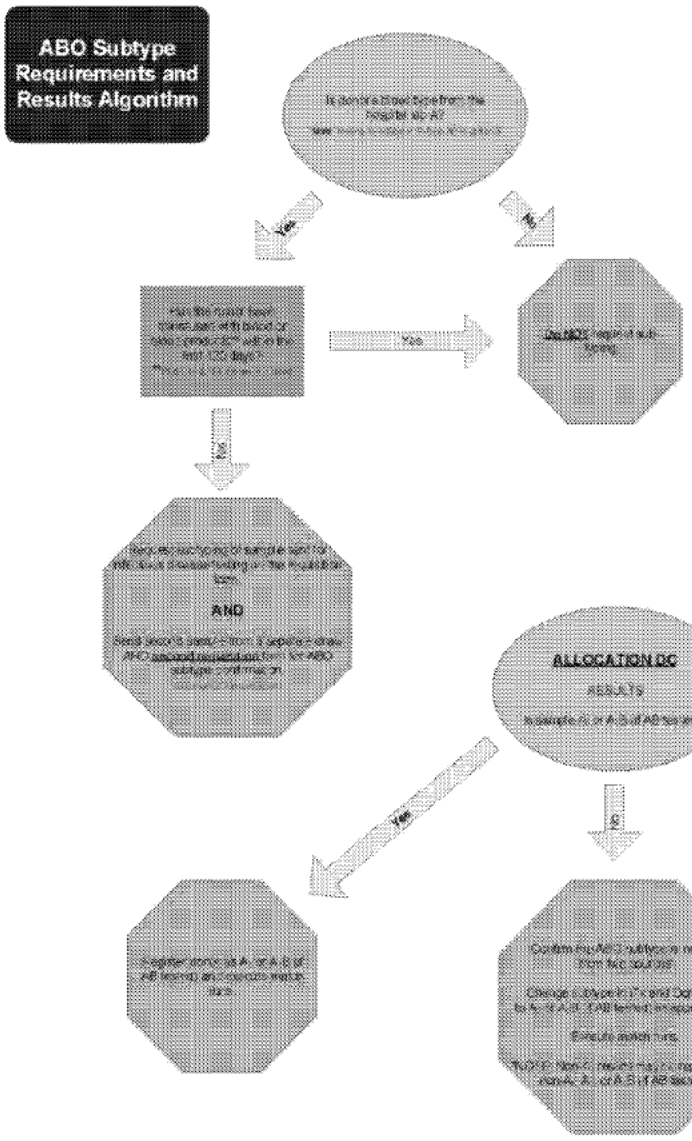
- Document the circumstances in the progress notes of the electronic donor record.
- Verbally communicate the circumstances to all receiving transplant centers.
- Include a statement in Donor Highlights section of DonorNet. Samples:

  9.5.10..1. Donor with UNOS ID WXYZ123 has an undetermined ABO after multiple testing attempts. We have conferred with our CMO and decided to identify the donor as type X. This is the most restrictive type indicated by the incongruent results. Recipients matching the blood type as listed should be compatible regardless of how the results are interpreted.

  9.5.10..2. Donor with UNOS ID WXYZ123 has an undetermined ABO after multiple testing attempts. We have conferred with our CMO and opted to identify the donor as type AB to minimize risk of incompatibility given recipients on the match should be AB and "universal recipients" with immunologic compatibility to any ABO.

- Print multiple copies of the statement for use in the Operating Room. Attach copies to ABO verification paperwork (e.g. ABO Verification and OR Time Out Checklist and Verification of Labeling and Packaging form) and include copies with source ABO documents that accompany each organ.
- Attach results of every additional ABO test to DonorNet and include results of every ABO test with each organ.

7.1 Attachment – ABO Subtype Requirements and Results Algorithm



[redacted]

From: [redacted]@dnwest.org
Sent: Thursday, February 4, 2021 12:03 AM
To: [redacted]
Subject: RE: Secure: UNOS Correspondence - CADN - Donor [redacted]
Attachments: [redacted] ABO Mismatch - Additional Information Binder.pdf

Hi [redacted]

My apologies. I realized I didn't send this before leaving work today.

Attached is a status update on corrections and additional information regarding this event.

Again, I apologies for the late nature of this communication.

[redacted]

From: [redacted]
Sent: Wed, 27 Jan 2021 13:16:06 +0000
To: [redacted]
Cc: [redacted]@dnwest.org'
Subject: Secure: UNOS Correspondence - CADN - Donor [redacted]

Please find the attached correspondence in reference to Donor ID [redacted] If you have any questions, feel free to contact me at [redacted]

***A note regarding the COVID pandemic**: The UNOS Incident Handling team understands the operational strain many in the OPTN community are experiencing as a result of the ongoing COVID pandemic. Should your team be unable to accommodate the due date listed above, please reach out to me so that we can discuss an alternative arrangement. We are making every effort to accommodate the needs of our members while continuing to fulfill our obligation to the community by monitoring the patient safety and/or public health-related concerns associated with organ donation and transplantation occurring within the OPTN.*

2/3/2021

[redacted]
Safety Analyst
UNOS Member Quality
United Network for Organ Sharing
[redacted]

Regarding: Confidential Medical Peer Review of [redacted] – ABO Mismatch – Additional Information

Dear [redacted]:

Thank you for the opportunity to provide additional information regarding this Medical Peer Review. We would like to provide an update regarding our planned corrections:

1. Please find the approved version of the ABO procedure, which has changed slightly from the Draft version submitted on 1/14/2021.
2. Please find the approved HARD STOP procedure that was in draft as of 1/14/2021 and now being implemented.
3. We also met with our testing lab and modified the process by which we are notified of cancelled ABO results. Our Clinical Operations Managers are being notified of any cancelled ABO results in real time. We have also worked with our testing lab to assess indeterminate ABO results. We recently received notification that the laboratory is switching to a new testing platform at our local lab and their labs throughout the country.
4. Our ABO training curriculum now includes scenario training / effectiveness checks. Training and competencies to the new ABO and HARD STOP procedures are in progress.
5. We received and are including an assessment from a panel of experts that reviewed our case.

We are committed to a complete understanding and correction of this event.

Sincerely,

[redacted]

DONOR NETWORK WEST

Title: ABO and Subtype Testing and Verification		
Document Number: **SE-P-011.00**	Page Number: **1 of 6**	Effective Date: **02/15/21**

1.0 PURPOSE:

1.1 The purpose of this procedure is to describe the Donor Network West (DNWest) policy which mandates the determination of two separate blood group determinations on all potential organ donors in compliance with UNOS/OPTN policy.

2.0 SCOPE:

2.1 This procedure applies to all potential organ donors.

3.0 RESPONSIBILITIES:

3.1 Qualified Health Care Professionals (QHCP) - Organ Program staff responsibility to:

3.1.1 Obtain two separate ABO and subtype (if applicable) determinations.

3.1.2 Use all source documents to determine donor blood type and subtype (if applicable).

3.1.3 Enter and verify the donor's blood type and subtype (if applicable) in the Donor Network West Electronic Donor Record (DONOR RECORD) and DONORNET.

3.1.4 Make all blood type documentation and transfusion history available in DONOR RECORD and DONORNET.

4.0 REFERENCES:

4.1 AOPO Standards

4.1.1 CL 6.6.1 *Verification of Donor ABO Type/Subtype if applicable*

4.2 CMS 42 CFR Parts 413, 441, 486 and 498: Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations (OPOs)

4.2.1 § 486.344(d)(2)(i) The OPO is responsible for two separate determinations of the donor's blood type.

4.3 UNOS Standard

4.3.1 Policy 2.6: *Deceased Donor Blood Type Determination and Reporting*

4.3.2 Policy 3.3: *Candidate Blood Type Determination and Reporting before Waiting List Registration*

4.3.3 OPTN Guidelines: *Guidance for ABO Subtyping Organ Donors for Blood Groups A and AB*

4.3.4 OPTN: *Guidance on Blood Type Determination*

4.4 Donor Network West Policy

4.4.1 AL-P-001 DONORNET, MATCH RUNS, AND ALLOCATION DOCUMENTATION

4.4.2 SE-P-013 INFECTIOUS DISEASE TESTING AND NOTIFICATION OF RESULTS

4.4.3 SE-P-014 HARD STOP PROCESS

5.0 DEFINITIONS:

5.1 *ABO Blood Type* – The classification of human blood into four groups: A, B, AB, and O. Also referred to as Primary Blood Type.

5.2 *ABO Subtyping* – A serological testing process that is performed to identify ABO phenotypes (e.g. typing for the blood group). This applies to all donors who are ABO group A only (AB subtype is optional).

5.3 *Conflicting* – Two blood tests from the same donor or candidate that present with different blood typing results.

5.4 *Indeterminate* — A blood test that does not provide a clear result. Examples include: indeterminate, cancelled, invalid, inconclusive, equivocal, pending, etc.

5.5 *Protocol* – A predefined written procedural method.

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5.6 *Qualified Health Care Professional (QHCP)* – A person who is qualified to perform blood type reporting or verification requirements. Professionals include personnel from the organ program who are trained to perform these procedures.

5.7 *Source Document* – An original record of the test results (or a photocopy or digital copy of the original record) documenting the donor's blood type from the laboratory that performed the blood type testing. This must be a printed report generated from the hospital or non-hospital laboratory.

5.7.1 A unique patient identifier must appear on the document on which the ABO is recorded.

5.7.2 The laboratory name must appear on the document on which the ABO is recorded.

Note: The source document with the hospital name already on it will be used, or the hospital name will be manually stamped onto the ABO page. If those options do not exist, the hospital name will be handwritten, and the entry will be dated and initialed.

6.0 DOCUMENTATION / FORMS:

6.1 OR-F-025 ABO VERIFICATION AND OR TIME OUT CHECKLIST

6.2 OPTN Organ Tracking System (TransNet, DONORNET)

7.0 ATTACHMENTS:

7.1 ABO Subtype Requirements and Results Algorithm

8.0 MATERIALS / SUPPLIES:

8.1 None.

9.0 PROCEDURE:

9.1 APPLICABILITY

9.1.1 ABO Typing is required for all donors. Subtyping is required and will be requested when the following three conditions are met:

- The donor is more than 3 years old;
- The donor's ABO blood type is A or AB (AB is optional); and
- Both subtype determinations can be made on samples collected before transfusion with red blood cells (transfusion of blood or blood products in the previous 120 days can affect results; however, plasma or platelets will not affect the determination of the A subtype).
- Refer to Attachment 7.1 ABO Subtype Requirements and Results Algorithm.

9.1.2 Allocation of organs will be based on the donor's primary blood type without consideration of subtyping in any of the following instances:

- The laboratory is unable to interpret subtype results;
- Subtyping results are conflicting or indeterminate;
- Allocation has begun prior to subtype results being confirmed.

9.2 ABO (AND SUBTYPE IF INDICATED) TESTING REQUIREMENTS

Refer to SE-P-013 INFECTIOUS DISEASE TESTING AND NOTIFICATION OF RESULTS for instructions on collecting and submitting blood for ABO and infectious disease testing.

The DNWest on-site coordinator shall be responsible for obtaining two separate ABO type determinations (and subtype if indicated) that meet the following requirements:

9.2.1 Two separate samples for ABO type (and subtype if indicated) must:

- Be drawn on two separate occasions,
- Have different collection times (at least 5 minutes must elapse between draws);
- Be submitted as separate samples.

9.2.2 One of the ABO type (and subtype if indicated) samples must be tested by a non-hospital lab or a hospital lab other than the lab at the donor hospital.

9.2.3 If the patient has received transfusions with type O blood at any time associated with the current clinical event (e.g. by paramedics, at a hospital or emergency department prior to the current hospital, etc.), one of the ABO type (and subtype if indicated) results must be performed on pre-transfusion blood. If no pre-transfusion blood is available, consult the DNWest CMO.

9.2.4 Documentation

- For all blood type A donors, document in the DONOR RECORD either that subtyping was completed or the reason it could not be completed.

9.2.5 Attach ALL ABO (and subtyping if indicated) source documents (including indeterminate or cancelled) in the Donor Record and in DonorNet.

9.3 BLOOD TYPE DETERMINATION

Blood type determinations must be made as follows:

9.3.1 All known available primary blood type (and subtype if indicated) tests must be finalized and source documents obtained to make a blood type determination.

9.3.2 Source documents must be verified to ensure that they:

- Contain blood type (and subtype if indicated) results for the donor.
- Indicate the same blood type (and subtype if indicated) on the test results.
  - If any *subtyping* does not indicate the same result, do not indicate a subtype in the DONOR RECORD or in DonorNet, and allocate based on *primary* blood type only.
- If results are conflicting or indeterminate, refer to OPTN Guidance for ABO Subtyping Organ Donors for Blood Groups A and AB and follow instructions in section *9.5 Conflicting or Indeterminate Primary Bood Type Results*.

9.3.3 Two qualified health care professionals (QHCP), one of which must be a Clinical Operations Manager (COM), will make an independent determination of blood type. Both QHCPs must enter and verify blood type determination in the DONOR RECORD.

9.3.4 ABO verification status will be discussed in the DNWest Pre-Allocation Huddle (PAH) to ensure that:

- All transfusion history is accounted for;
- There are no transfusions with red cells prior to ABO Subtyping (if applicable);
- All tests have been finalized, results obtained, and uploaded to DonorNet;
- One test is from a non-hospital lab or hospital other than the donor hospital.

9.3.5 Upon completion of DNWest PAH and consensus regarding donor blood type, two QHCPs must independently enter and verify blood type (and subtype if indicated) determination in the DonorNet Donor Summary.

9.3.6 The deceased donor is not eligible for a match run until DNWest completes the blood type determination and verification process and addresses any indeterminate scenarios.

9.3.7 If this verification process cannot be completed due to an expedited donor process, it may be completed after the match run, but prior to organ release to a transplant hospital in order to avoid organ waste. Document the following in a progress note in the DONOR RECORD:

- The reason that both blood type tests could not be completed, verified, and reported prior to the match run;
- If there are conflicting or indeterminate primary blood type test results, refer to section *9.5 Conflicting or Indeterminate Primary Bood Type Results* to address

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the discrepancy and re-execute the match run if the final ABO result is different from the initial ABO on the original match run;

- That all required blood type and subtype requirements, determinations, verification, and reporting were completed prior to organ release to a transplant hospital.

9.4 RECOVERY BLOOD TYPE DOCUMENTATION AND REPORTING

9.4.1 Upon recovery team arrival and prior to incision, the on-site coordinator, who is a QHCP, will review the entire donor record and will verify the donor ID, ABO and subtype (if applicable), and organs to be recovered (including laterality) using source documents and acceptable sources, with each lead recovery surgeon/personnel.

9.4.2 The ABO VERIFICATION AND OR TIME OUT CHECKLIST will be signed by the on-site coordinator and each lead recovery surgeon/personnel.

9.4.3 A copy of page one of the signed ABO VERIFICATION AND OR TIME OUT CHECKLIST with the ABO Verification section completed will be:

- Included in the donor record that accompanies each organ;
- Uploaded to the DONOR RECORD; and
- Uploaded in DonorNet.

9.5 CONFLICTING OR INDETERMINATE PRIMARY BLOOD TYPE RESULTS

The purpose of this section is to ensure recipient safety by establishing a consistent method for addressing and resolving conflicting or indeterminate primary blood type results.

Factors impacting blood typing reliability may include, but are not limited to: transfusion, ABO non-identical stem cell transplant, infections and cancers, elevated globulin levels, A-weak, B-weak, and blood type subgroups, immunosuppression, and age (under 6 months). (See OPTN Guidelines: *Guidance for ABO Subtyping Organ Donors for Blood Groups A and AB.)*

Should a conflicting or indeterminate ABO test occur, the following steps should be taken:

9.5.1 Initiate a HARD STOP. The DNWest CMO must be contacted immediately to guide the process of determining blood type, including contacting the Blood Banks and reference labs and UNOS to obtain the information required to determine the course of action.

9.5.2 If offers have been made, the DNWest CMO will communicate circumstances to affected surgeons.

9.5.3 A primary blood type, from the current clinical event, conducted prior to any transfusion should be used as the standard for the match run.

9.5.4 Contact all blood banks and infectious disease testing labs associated with the donor's current admission course starting with the originating hospital and confirm ABO testing and transfusions received. Consider possibility of pre-hospital administration of blood products.

9.5.5 If available, obtain [redacted] blood type results for reference.

9.5.6 Initiate a huddle with the OAC, CPC, COM, CMO, and AOD to establish a plan and document in DONOR RECORD. Blood banking physicians and scientific experts should be consulted, as needed, to review the entirety of the circumstances such as:

- Massive transfusion without a pretransfusion sample.
- Result comments suggesting a different underlying type.
- Discrepancies between forward (antigen) and reverse (antibody) typing.
- Laboratories reporting invalid or inconsistent testing.

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9.5.7 When efforts to resolve the discrepancy have been exhausted, the following match run sequence should take place with the more restrictive blood type to be utilized for the match run. A pre-transfusion specimen should be used as the standard for the match run. Situations in which this would occur include blood transfusions administered via massive transfusion protocol prior to, and/or in between, blood draws.

- A blood type and O blood type = match run on A blood type.
- B blood type and O blood type = match run on B blood type.
- AB blood type and O blood type = match run on AB blood type.
- A blood type and AB blood type = match run on AB blood type.
- B blood type and AB blood type = match run on AB blood type.

9.5.8 When donor blood typing results remain in conflict and unable to be resolved, the safest course of action is to consider the donor to be blood type AB to ensure that only AB blood type candidates, as universally ABO compatible recipients, would be considered to receive the organs from that donor.

9.5.9 Document and communicate the circumstances as follows:

- Document the circumstances in the progress notes of the DONOR RECORD.
- Verbally communicate the circumstances to all receiving transplant centers.
- Include a statement in the Donor Highlights section of DonorNet. Samples:
  - Donor with UNOS ID WXYZ123 has an undetermined ABO after multiple testing attempts. We have conferred with our CMO and decided to identify the donor as type X. This is the most restrictive type indicated by the incongruent results. Recipients matching the blood type as listed should be compatible regardless of how the results are interpreted.
  - Donor with UNOS ID WXYZ123 has an undetermined ABO after multiple testing attempts. We have conferred with our CMO and decided to identify the donor as type AB to minimize risk of incompatibility given recipients on the match should be AB and "universal recipients" with immunologic compatibility to any ABO.
- Print multiple copies of the statement for use in the Operating Room. Attach copies to ABO verification paperwork and include copies with source ABO documents that accompany each organ.
- Attach results of every ABO test to DonorNet and include results of every ABO test with each organ.

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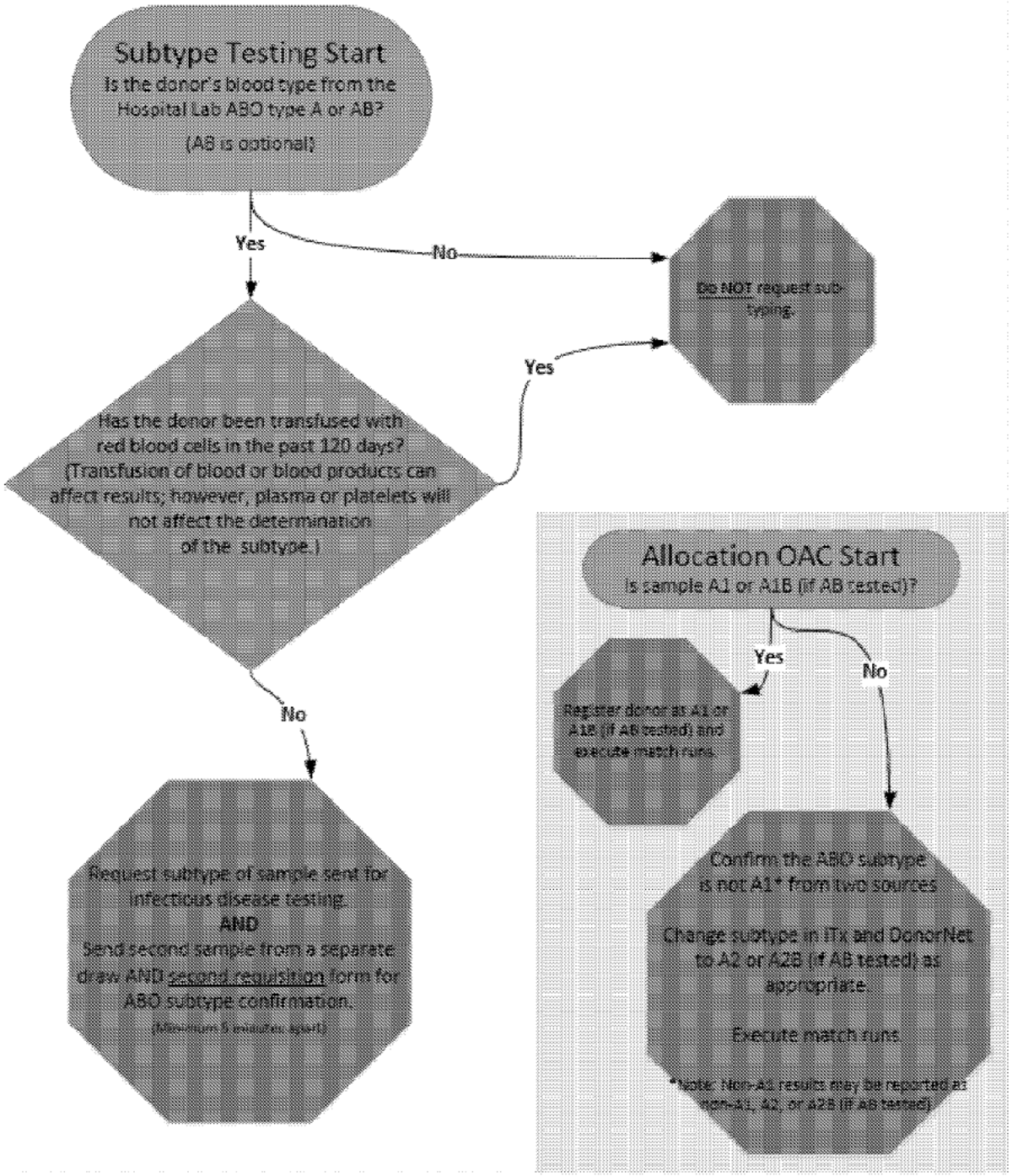
7.1 Attachment – ABO Subtype Requirements and Results Algorithm



OPTN

Guidance on Blood Type Determination

Conventional Methods for ABO determination

ABO blood type testing is generally performed using one of three methodologies: tube, gel, or solid phase. Tube methodology is a manual method using separate test tubes for each reaction. Gel column agglutination methodology uses gel or glass beads. Red blood cells and antibodies are combined in microtubes filled with gel matrix, then centrifuged to force the red blood cells through the column. Agglutinated (or clumped) cells remain trapped at the top of the gel column, while non-agglutinated cells travel through to the bottom. In solid phase methodology, A and B antigens or antibodies are adherent to microtiter wells, and red blood cells or serum is added. After washing, indicator red blood cells coated with anti-Immunoglobulin G (IgG) are then added to determine if agglutination occurred. Various platforms have been developed for automation or semi-automation of gel and solid phase methods.

For each of these methodologies, ABO blood group is determined by performing both a forward and reverse blood type. The blood sample is first centrifuged to separate the red blood cells from the plasma or serum. For the forward blood type, red blood cells are combined with reagent anti-A, anti-B, and anti-D antibodies in three reactions to determine the presence of ABO and RhD antigens. The reverse blood type uses the patient's plasma or serum, combined with reagent group A and group B red blood cells, to determine which ABO antibodies are present.

The forward and reverse blood type results should be consistent in order to report the final blood type. If there is a discrepancy between the forward and reverse blood type results, the cause of the discrepancy should be determined prior to reporting a blood type. If the discrepancy cannot be resolved, most transfusion services will treat the patient as blood type O for transfusion purposes until the correct blood type can be determined.

Factors Impacting Blood Typing Reliability

Several clinical situations may result in unreliable serologic blood typing which can lead to mixed field reactions or discordances in the forward and reverse blood typing.

1. **Transfusion:** Patients who receive type O transfusions in emergency situations will often develop a mixed field or discordant typing. Forward typing (patient RBC mixed with commercially available antibody) will be mixed field or non-agglutinated due to the transfused type O red cells, whereas reverse typing (patient plasma mixed with commercially available reagent RBCs) will detect the patient's native anti-A or anti-B antibodies, leading to discordant or indeterminate reports.

   Although case reports have described transfusion impacting a patient's blood type on a temporary basis, there is no information in the literature regarding a time frame post transfusion in which there could be certainty that the blood type results are reliable and no longer impacted by the transfused cells.

2. **ABO Non-identical Stem Cell Transplant:** Patients who have received stem cells from a donor with a different blood type will display a mixed blood type until full engraftment occurs. After engraftment, they will display a different blood type in circulating whole blood from that of the organ allografts.

   Organ donors who have previously received stem cell transplants should be given careful consideration. This information needs to be considered by the OPO medical director and histocompatibility lab. Peripheral blood is typically used for tissue typing on a deceased donor, but

in these patients who are prior recipients of stem cells, buccal swabs or lymph nodes need to be utilized to determine both blood type and Human leukocyte antigen (HLA) since the organs and tissues will be incongruent from circulating blood.

3. **Infections and Cancers:** While uncommon, some patients develop an "acquired B" phenomenon as a result of a bacterial infection or malignancy. The underlying infection can cause enzymatic alteration of the group A antigen on cells, and can result in the formation of a "B-like" antigen and discrepant blood type testing. This has been described in patients with specific *Escherichia coli* infections as well as in patients with malignancies of the stomach and intestine.[2] In addition, neonates with Necrotizing Enterocolitis due to *Klesbiella pneumonia* have been inadvertently assigned as blood type B due to the "acquired B" phenomenon.[3] It should also be noted that detection of acquired B is dependent on the anti-B clone used and reagent pH.
4. **Elevated Globulin Levels:** Patients with multiple myeloma, amyloidosis, hyperfibrinogenemia, Waldenstrom macroglobulinemia, plasma cell disorders or those who receive plasma expanders, such as dextran, may display a protein to plasma abnormality. This can lead to rouleaux formation and false appearance of agglutination on forward typing that may be inconsistent with reverse typing.[4]
5. **A_{weak}, B_{weak}, and Blood Type Subgroups:** Antigen expression can become so weak that it is not detected by forward typing, with no natural antibodies present on the reverse reaction. In addition, some subgroups may not express some forms of the blood type red blood cell (RBC) antigens, which can cause discordant forward and reverse patterns. For example, patients with type A_2 may possess anti-A_1 antibody (estimated in 1-8% of A_2 individuals and 22-35% of AB individuals) [5], which would render the reverse typing discordant from forward typing. Such patients would display forward type of A, but reverse type of O in the event that antibodies to A_1 are present in the type A_2 patient.[6]
6. **Age:** Patients that are very young or elderly may have weakly reacting antibodies, or missing antibodies that renders the blood typing incongruent.

   It is well described that while newborns express A and B blood type antigens, which would be detectable on forward typing, they do not produce antibody to blood types until 3-6 months of age. Until this age, the blood type antibodies present are maternal from placental transfer.[7] Newborns should only be typed using forward typing, as reverse typing may result in discordant or unreliable results. If a newborn has received any type O transfusion, extreme caution should be exercised with regard to organ donation, as the newborn can be incorrectly typed as O using forward typing only.

   Similarly, elderly patients may not possess enough antibody for reliable reverse typing, resulting in discordance. In one study, a 66 year old otherwise healthy patient was deemed to be type O on forward typing, but did not show anti-A or anti-B on reverse typing until the amount of serum utilized in the testing was doubled.[8] This would result in a discordant forward type O and reverse type A, B, or AB.
7. **Immunosuppression:** Patients severely immunocompromised, due to disease, therapy, or depressed immunoglobulin levels may not mount an appropriate amount of antibody to reliably perform reverse typing, for the same physiologic reasons mentioned above.[9]

Acceptable Blood Type and Transfusion Sources

OPOs rely on a number of potential sources for donor blood type testing. Commonly these may be the donor hospital blood bank, the OPOs contracted infectious disease laboratory and/or the OPOs tissue

typing laboratory. OPTN Policy requires at least two sources of ABO type from donor samples drawn at separate times and ideally these samples would be obtained prior to transfusions which may impact blood typing results. If a potential donor was treated at another hospital prior to transfer to the donor hospital or recovery center that originating hospital may have pre-transfusion samples available for testing.

All known and available blood type results of the donor should be reviewed to ensure there are no conflicting results. To have, for example, two recent blood typing results that are in conflict with a historic blood type from a previous hospital admission should call into question the reliability of blood typing results and action must be taken to resolve this conflict.

Though historical blood typing results may be available from past hospitalizations these results may be used only as a means of confirming blood typing performed during the donor's current admission course rather than as a primary source of the donor's blood type. The best source of ABO typing by blood sample is ideally a sample obtained prior to the donor receiving blood transfusions.

As referred above in the section titled "*Conventional Methods for Blood Type Determination*", donor blood typing determination performed by hospital blood banks considers the perspective of the patient as a blood product recipient. Thus, if there are discrepant forward and reverse blood typing results the blood bank may err on the side of assigning the result as blood type O to ensure the patient would receive blood type compatible O blood transfusions. This of course creates a concern if that patient then becomes an organ donor and the reliability of donor blood type may be in question.

When considering the reliability of blood type results transfusion history must be considered as it can impact the reliability of such testing. It is important for OPOs to consider what blood products the donor may have received in all phases of the admission course, including pre-hospital or any other hospitals where the patient may have been treated prior to a transfer to the donor hospital or recovery center.

Alternative (new) Testing Methods for Determination of Blood Type: DNA-based Determination of Blood Type

Since the early 1900s, blood typing has been performed by serological methodology.[10] This has consisted of a forward and reverse typing which together are evaluated and must agree to give a valid blood type phenotype. However, when patients have been transfused out of their own blood type, or discrepancies between the forward and reverse typing or mixed field typing is seen, DNA based testing may be considered.

Advances in technology allow for blood type genotyping using molecular methods. These include:

- Sanger sequencing
- Polymerase chain reaction (PCR) with restriction fragment length polymorphism analysis (PCR-RFLP)[11]
- PCR using sequence-specific primers (PCR-SSP)[12]
- Real-time quantitative PCR[13]
- High density DNA arrays[14]
- Next generation sequencing (NGS)[15-23]

All of the above genotyping methods originated under research protocols as research use only (RUO) and have been implemented for clinical testing in a small number of large reference labs as laboratory in house developed assays (LDT) evaluated in concert with serologic reactivity of the sample. This has

limited the number of labs capable of performing ABO genotyping. However, recent vendor supplied kits have been developed for blood type genotyping using PCR-SSP, real-time PCR, and targeted NGS. Importantly, all of these vendor supplied kits use techniques and instruments already employed by most tissue typing labs. As such, the PCR-SSP and real-time PCR methods are of particular importance for deceased donor testing, since they can be done within the required time constraints. Of these, real-time PCR is the most attractive method for deceased donors since it has a streamlined assay setup and the PCR products are detected by the instrumentation allowing for automated interpretation by vendor supplied software. Real-time blood type genotyping could be routinely performed alongside existing histocompatibility typing lab workflows on deceased donors to resolve serologic forward and reverse blood typing discordances, help interpret mixed-field reactions, and when evaluated with serologic blood typing by subject matter experts can resolve the inherited blood type, especially in situations of massive red blood cell transfusion.

Further information can be found in the appendix.

Triggers for When to Use Alternative Methods

In those circumstances where blood typing results may be in question OPOs should perform a thorough review of all results, including the specific forward and reverse typing results, to ensure there are no discrepancies or unreliable results.

Certainly in situations where there are conflicting donor blood typing results OPOs are required to have written protocols in place to attempt to resolve the conflicting results.
More importantly, in the circumstances where a donor has received blood products prior to the availability of required samples for donor blood typing, the potential impact on post-transfusion results should be considered.

In any circumstances where there are blood typing results received by the OPO that are "Indeterminate" due to conflicting forward and reverse blood typing, all results should be reviewed. These results should be viewed in conjunction with transfusion history, donor medical history and admission course for factors that may have led to an indeterminate result which then may call into question other results received.

Practices to Resolve Donor Blood Type Conflicts

There are a variety of practices employed by OPOs to resolve conflicting or indeterminate donor blood typing results.

Resolution of indeterminate results may be achieved with a review of donor transfusion history and review of blood type forward and reverse typing results. In some scenarios a donor may express blood type O by forward typing and a different blood type by reverse typing when the donor has received un-crossmatched blood type O transfusions which can convolute the forward typing result.

For example, if a donor receives massive transfusions of blood type O packed red blood cells (PRBCs), then blood type forward-typing indicates blood type O with reverse-typing indicating blood type A, it is likely the blood type O blood transfusions have affected the forward typing by reflecting the blood type of the transfused PRBCs. In such a scenario, the safest course of action is to conclude the donor is blood type A. Concluding that the donor is blood type O in error would potentially expose transplant candidates to organs that are incompatible for transplant. By concluding the donor is blood type A in this scenario (subtyping in this scenario would not be an option) then all candidates matched to the

donor would be ABO type A or AB (or Platelet Transfusion Refractory (PTRs) listed as accepting organs of incompatible blood type as allowed by policy).

It is best in such scenarios to consult with blood banking physicians and scientist experts to review the entirety of the circumstances, donor medical history, transfusion history and blood type results to ensure the safest course is followed when the final determination of donor blood type is made. If there is doubt about the conclusions of donor blood typing, extreme caution should be exercised to avoid the possibility of exposing candidates to such risk.

Conflicting blood typing results are certainly the more concerning scenarios OPOs may face. In the event the donor blood typing by one lab or blood draw time is conclusive but conflicting with the conclusive results of another lab result or result on a donor blood sample drawn at a different time, the OPO should review of donor transfusion history and review of all forward and reverse blood type results obtained to determine the source of the conflict. The reliability of the blood sample source must also be called into question in such a scenario. OPO Medical Directors and Blood Bank Experts should be consulted to investigate the source of the potential error.

OPTN policy requires that blood type be determined using two blood samples drawn at separate times. The purpose of this requirement is to confirm blood type determination and ensure that samples have been drawn from the correct patient to prevent conflict that may have occurred due to possible sample labeling error.

Some OPOs have employed policies to re-draw donor blood samples after an interval of time has passed and have the samples re-tested for blood type. While this may resolve some conflicts it may not always be a reliable means since no criteria is known for determination of when a donor would revert to their natural blood type. Re-testing may result in further conflict or such a practice may result in blood type results that are no longer in conflict and enable more confidence in the original result.

The utilization of alternative (new) testing methods for determination of blood type DNA-based determination of blood type as described above could be an adjunct in efforts to resolve conflicting, discrepant or indeterminate blood type results.

As a last resort, when donor blood typing results remain in conflict and unable to be resolved, the safest course of action is to consider the donor to be blood type AB to ensure that only AB blood type candidates, as universally ABO compatible recipients, would be considered to receive the organs from that donor. This does however carry the consequence that urgently ill candidates in need of a lifesaving transplant may be excluded from consideration of the organs in such a scenario.

Acknowledgements:
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Appendix

DNA-Based Determination of ABO

When the ABO gene was cloned in 1990, it was found that the genes for A the B glycotransferase enzymes differ by four single nucleotide polymorphisms (SNPs) in exon 7, designated according to the cDNA sequence as c.562C/G (p.176Arg/Gly), c.703G/A (p.235Gly/Ser), c.796C/A (p.266Leu/Met), and c.803G/C (p.268Gly/Ala). Group O, representing loss of transferase activity, most often resulted from a nucleotide deletion in exon 6, c.261delG (p.Thr88Profs*31), although a number of other genetic backgrounds have been reported.[24] To date, several hundred different ABO allele sequences have been catalogued by the International Society of Blood Transfusions (ISBT) Red Cell Immunogenetics and Blood Group Terminology working party, however this is not a comprehensive list and new alleles are still being discovered primarily associated with weaker than expected antigen expression (i.e. A and B subgroups) that can cause serologic typing discrepancies between forward and reverse ABO typing .[25] The ABO subtypes (e.g. A_2, A_{weak}, A_x, B_3, B_{weak}) are associated with genetic changes elsewhere in the coding, or less often regulatory, region of the ABO gene. Importantly, although numerous A and B alleles have been defined, the original four SNPs are the essential differences that distinguish the A and B phenotypes. Group O is most often associated with homozygosity for the nucleotide deletion in exon 6, c.261delG, although to date, at least 15 other genetic changes have been found to cause an O phenotype.[26] Methodologies for ABO genotyping target the A and B exon 7 SNPs along with one or more of the known O genetic changes. Some of the assays also include the more common A_2 subtype.

ABO genotyping by exon specific amplification and Sanger sequencing allows for unbiased evaluation of the ABO gene, enabling detection of rare and novel ABO genetic changes, although Sanger sequencing is unable to define the cis/trans haplotype phase of heterozygous changes. This can be overcome by using primers specific to A, B, or O alleles to amplify the target or in the sequencing reaction. For routine clinical sequencing, Sanger sequencing is performed for ABO exons 6 and 7, and when serologic reactivity suggests the presence of a subgroup phenotype as the basis for a discrepant forward and reverse type, the remainder of the gene is sequenced including promoter regions located upstream of the ABO gene within intron 1 associated with weakly expressed ABO subtypes.[27,28] Sanger sequencing is not scalable for testing large number of samples and the results require interpretation by subject matter experts.

One of the first ABO genotyping assays was based on polymerase chain reaction (PCR) amplification of ABO exons 6 and 7 followed by restriction fragment length polymorphism analysis (PCR-RFLP).[29] Since this PCR-RFLP assay can distinguish between A, B, and the two most common O genetic backgrounds it is still used by reference labs as an initial assay in ABO genotyping workups (only two American Association of Blood Banks (AABB) accredited reference laboratories in the United States do ABO genotyping) as RUO LDT testing. The PCR-RFLP assay requires subject matter expert interpretation of the restriction enzyme digestion patterns.

ABO genotyping methods targeting multiple SNPs have proven to be scalable, and reliable. For example, allele specific PCR using sequence-specific primers (PCR-SSP) have been developed to determine ABO genotype using by targeting the key ABO genetic changes.[28] These PCR based methods have also been extended to use real-time quantitative PCR to simplify detection and allow for automated software based interpretation.[30] One benefit of PCR based methods is that allele specific phasing reactions can be incorporated into them to define the cis/trans haplotype of important genetic positions. Recently the

use of a high density SNP array have also been reported for a scalable ABO genotyping method in large population level datasets capable of genotyping thousands of samples per batch.[31]

Several groups have recently published the use of both short and long read next generation sequencing (NGS) for ABO genotyping from whole genome sequencing, whole exome sequencing, and targeted NGS,[32–40] including the use of automated interpretive software.[32,35,36] One of the major advantages of NGS is that it allows for evolution of the entire ABO gene including novel genetic changes. In addition, in most cases short read NGS can fully phase the most import genetic changes, which when combined with long read NGS can fully phase the entire ABO gene. In addition, by running hundreds of samples per batch targeted NGS can reduce the per sample cost of ABO genotyping. However, current NGS methodologies still require several days for library preparation and sequencing.

Although, transfusion of red blood cells can interfere with serologic ABO typing, blood group genotyping, including ABO, has been shown to not be influenced by transfusion.[41–44] This is because blood group genotyping, like HLA molecular typing, is performed using genomic DNA isolated from recipient white blood cells which are generally not affected by red blood cell transfusion. However, in situation of granulocyte transfusion or stem cell transplant, ABO genotyping results need to be interpreted based on the clinical context.

ABO genotyping has proven to be highly accurate across methodologies, including some studies of deceased donors. Targeted NGS of just ABO exon 6 and 7 with automated software interpretation was 99.6% concordant to serologic ABO testing in 453 samples, with two discordances likely due to false negative serologic testing from weak expression.[34] NGS based whole exome sequencing with automated software interpretation of ABO exons and nearby intronic regions was 100% concordant with ABO serologic testing.[40] NGS based whole genome sequencing and automated software based evaluation of the entire ABO gene in 200 samples was 100% concordant with serologic ABO typing.[36] Targeted NGS of the entire ABO gene has also been applied to a set of 40 discordant serologic cases, in which it was able to explain the majority of discordances by identifying ABO alleles encoding ABO subtypes, weak ABO variants, hybrid ABO enzymatic activity, and novel genetic changes.[38,45] Most recently, targeted NGS of ABO exons 2 to 7 with automated software interpretation of 100 deceased donors was 100% concordant with serologic ABO typing.[46] Similarly, ABO genotyping with PCR-SSP and real-time PCR in 500 deceased donors was 100% concordant with ABO serologic typing and clarified discordant forward and reverse reactions, mixed field serology, and weak anti-A_1 lectin results.[47]

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Title: HARD STOP Process		
Document Number: SE-P-014.00	Page Number: 1 of 2	Effective Date: 02/15/21

1.0 PURPOSE:

1.1 The purpose of this document is to describe a procedure for escalating patient safety concerns and stopping the donation process upon identifying information that could affect patient safety or have other serious consequnces. This escalation / HARD STOP is to ensure full review of all available donor patient medical information which could potentially affect staff and patient safety during transplant.

1.2 The procedure is intended to provide a clear process for all staff to express and resolve safety concerns.

1.3 The HARD STOP will prohibit setting or moving forward with a scheduled OR time until a resolution is reached or final suitability for donation is determined.

2.0 SCOPE:

2.1 The HARD STOP applies, but is not limited to: ABO Incompatibility/Indeterminate results, massive transfusion protocols, questionable brain death declaration and unresolved suspicion of cancers and/or infectious disease processes.

3.0 RESPONSIBILITIES:

3.1 All DNWest employees are responsible for identifying and excalating information that indicates a HARD STOP may be warranted to their management or directly to those listed in 3.2.

3.2 COMs, AODs, CEO, and CMO are responsible for activating a HARD STOP.

3.3 Only AODs or CMOs may release a HARD STOP. Once a HARD STOP is released, OR continuation or scheduling may proceed.

4.0 REFERENCES:

4.1 None

5.0 DEFINITIONS:

5.1 *Escalate* – To bring attention to, or raise awareness of, an issue. To report an issue to a person of higher responsibility.

5.2 *HARD STOP* – Term used to describe an inflexible stop in the donation process until potential safety issues can be resolved. A HARD STOP can only be overridden by AOD or CMO.

6.0 DOCUMENTATION / FORMS:

6.1 DNWEST ELECTRONIC DONOR RECORD (DONOR RECORD)

7.0 ATTACHMENTS:

7.1 None

8.0 MATERIALS / SUPPLIES:

8.1 None

9.0 PROCEDURE:

9.1 Identify Safety Concerns

9.1.1 All staff members may identify recipient safety concerns. Safety concerns may include but are not limited to:

- ABO incompatibility/Indeterminate results,
- massive transfusion protocols,
- questionable brain death declaration
- unresolved suspicion of cancers
- infectious disease processes

DONOR NETWORK WEST

Title: HARD STOP Process		
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9.2 Escalate Safety Concerns

9.2.1 All employees are empowered to escalate safety concerns and propose a HARD STOP.

9.2.2 Upon identification of a potential patient safety concern, communicate concerns to a manager for further assessment and escalation to COM, AOD, CMO.

9.2.3 Patient safety concerns may also be escalated directly to COM, AOD, or CMO.

9.3 Address Safety Concerns

9.3.1 A huddle to include COM, AOD, and CMO will be called to review and assess concerns.

9.4 Activate / Deactivate HARD STOP

9.4.1 A HARD STOP will be initiated if concerns cannot be immediately resolved and additional time is needed. The COM will initiate a hard stop as follows:

9.4.1.1 In the DONOR RECORD > TRACKING tab > REFERRAL SUMMARY page, change the Referral Status to HARD STOP.

9.4.2 HARD STOP will remain in effect until issues are resolved.

9.4.3 HARD STOP will be released upon resolution of concerns to satisfaction of COM, AOD, and CMO. COM will change the Referral Status to the applicable status / acuity.

9.4.4 HARD STOP will be communicated to all involved in the donation process.

Background

An incorrect donor blood type assignment by the OPO led to poor outcomes for recipients. This document is based on the information we have been provided and communicates our joint opinion focusing specifically on blood banking issues and actions that can reduce the likelihood of similar situations in the future.

Case Summary

A 15 y/o Hispanic male arrived at Hospital 1 on 12/14 after multiple gunshot wounds to the chest. He received massive group O trauma blood transfusions (including four whole blood units) before a blood sample was drawn for ABO typing. ABO blood group typing using standard serologic methods was resulted as group O. A comment was made on that blood type test; however, the comment was not initially available to the OPO team due to legibility issues. It was later clarified by the hospital to read the "TS was drawn after patient was stabilized and had received all the MTP boxes. Patient real type is unknown, but based on weak back-type, he may have been B pos."

He was transferred to Hospital 2 where he became an organ donor. The first blood type using standard serologic methods from Hospital 2, on 12/15, was reported as initially invalid, then resulted as group O. A repeat type again using standard serologic methods was performed at Hospital 2 on 12/20; which was also initially invalid, was then resulted as blood group O.

Standard serologic ABO typing was also requested from VRL on 12/20. Results from VRL showed the test was cancelled; however, on 12/21 the OPO learned that VRL had issues obtaining a valid result in house due to a mixed field result, so they referred the sample to another VRL facility for further testing.

The donor coordinator contacted UNOS on 12/21 and was advised to run the donor as group O with a prominent note in the donor highlights.

Organ recovery occurred on 12/22.

On 12/23, the VRL result came back as B positive.

According to a verbal report from the OPO, several organs, including heart, liver, kidney and simultaneous kidney/pancreas had been transplanted to group O recipients. Outcomes are as follows: the heart patient was put on ECMO and relisted for transplant, the liver is still implanted; the single kidney was removed, and the kidney/pancreas was also explanted.

Analysis

The main issue in this case is the uncertainty of the donor's ABO type. He was transfused with multiple units of group O blood including 4 units of whole blood, approximating 2 blood volumes; the effect of which was to dilute his own blood to the point that testing identified circulating group O blood red cells.

Standard serologic blood typing has both a forward typing component (which tests what antigens are observed on the surface of red blood cells (RBCs)) as well as a reverse typing component (which tests what antibodies are observed in the patient's plasma). The two components must match in order to unequivocally determine a blood type. This donor's forward typing at Hospital 1 showed the donor cells had no reaction with anti-A or with anti-B, which is consistent with group O RBCs in circulation. The reverse typing donor plasma reacted with reagent A cells and reagent B cells. This demonstrates the presence of anti-A and anti-B in donor circulation, which would be consistent with a group O donor. The reaction of donor plasma with type A reagent RBCs was stronger than the reaction of donor plasma with type B reagent RBCs (4+ vs 1+). This observation is congruent with the comment that the donor "may have been B pos". That comment was relevant and would have been helpful in recognizing a possible ABO discrepancy.

The OPO explored using ABO genotyping on donor derived DNA, which would be less prone to interference by transfusion. They reported being quoted a turnaround time of 3 days. Local, established ABO genotyping using RT-PCR should be able to obtain results in less than 2 hours.

The second issue is the handling of illegible test comments. A comment was initially received from Hospital 1 that gave a direct statement suggesting the donor may have been group B even though he typed as O due to massive transfusions. Given two blood group O results the OPO reported the blood type as O without further consideration to or follow up of the comments indicating there may be a discrepancy.

The third issue is the handling of cancelled and invalid tests. There were multiple tests initially resulted as invalid or cancelled; exploration of these may have indicated that the group O results may not represent the donor's original blood type.

Given that similar situations have occurred in the past, UNOS has recently updated their policy and guidance to include the use of ABO genotyping for identifying ABO type switching due to the transfusion and resolving discordant or unusual ABO serologic typing results. The OPO had 3 serological ABO determinations of group O. Although comments and invalid testing results should have raised concerns, those flags are not always available; so, they should not be relied upon to identify patients whose ABO typing may be misleading due to massive transfusions in the absence of a pre-transfusion ABO type.

Conclusions

We appreciate being consulted in this case.

Honoring the following observations will reduce the likelihood of future error:

There must be a hard stop on allocation activity whenever ABO is in question. Activity must stop until the questions are resolved; best practice is to resolve the questions by ABO genotyping. RT-PCR on blood isolated DNA would be less likely to be affected by interference due to transfusion. RT-PCR on buccal swab isolated DNA should be completely free from interference due to transfusion and should be considered if time is a factor. Although serologic ABO testing would still need to be performed, the adjunct of RT-PCR ABO genotyping could act as a safety net to help identify similar cases in the future. Although performing ABO genotyping on all deceased donors would be the safest option, at a minimum ABO genotyping should be performed for any of the following events:

- Massive transfusion without a pretransfusion sample.
- Result comments suggesting a different underlying type.
- Discrepancies between forward (antigen) and reverse (antibody) typing.
- Laboratories reporting invalid or inconsistent testing.

When the ABO type cannot be resolved or if there is doubt, the donor should be listed as group AB.

All testing information must be legible. Invalid or cancelled tests should be understood by the OPO. A result comment is part of the test result. Any illegible results or accompanying information must be clarified before accepting or entering the result. An "invalid" or "cancelled" test may suggest unusual conditions. When a result is invalid, the OPO should ask the testing laboratory to explain why it was resulted as invalid, even if it is subsequently changed to a valid result. When a test is cancelled, the OPO should ask the testing laboratory why it was cancelled. The reasons for any invalid tests or for cancellation by the performing laboratory should be brought to the attention of medical leadership for approval prior to proceeding with an ABO assignment or match run.

The OPO must continue to share any history of uncertainty surrounding ABO typing results with the transplant centers. ABO genotyping will not remove the need to communicate serologic ABO testing results, including those that were invalid, cancelled, mixed field, remain illegible, or are otherwise questionable. When ABO genotyping is performed, it will be helpful for the OPO to comment on questionable serologic results. Transplant centers must make their own critical medical assessment to determine whether and how uncertain results affect the risk of transplantation.

We would be pleased to help with any questions that arise.

About the Authors

[redacted] is the Histocompatibility Laboratory Director at Southwest Immunodiagnostics, Inc. in San Antonio Texas. She has more than 30 years of experience in histocompatibility and has served on many committees and boards for ABHI, ASHI, and other professional organizations. She is currently the past chair of the UNOS Histocompatibility Committee and serves on the Board of Directors at ASHI. [redacted]erved as a member of the UNOS ABO working group to develop a guidance document for ABO typing under the conditions of massive transfusion.

[redacted] the Director for Clinical Laboratory Informatics and the Medical Director for the Tissue Typing Laboratory at Brigham and Women's Hospital. He is board-certified in Blood Banking/Transfusion Medicine, Clinical Pathology, and Clinical Informatics. He is an internationally recognized expert on blood group genotyping and is an active member of AABB, ISBT, ASHI, and was also a member of the UNOS ABO working group.

[redacted] is the Director of the Transfusion Service and of the Histocompatibility Laboratory at Loma Linda University Medical Center. He is board-certified in Histocompatibility, Blood Banking/Transfusion Medicine, Clinical Pathology, and Clinical Informatics. He is an active member of AABB and ASHI.

7/14/2021

[redacted]
Compliance Operations Analyst
UNOS Member Quality
United Network for Organ Sharing
[redacted]

Regarding: Confidential Medical Peer Review of [redacted] – ABO Mismatch – Follow-up Questions

Dear [redacted]:

Please see below for answers to follow up questions:

1. Are there any updates on if the ABO genotyping mentioned in the CAP is available and logistically possible? If so, is CADN using that testing?

   ABO genotype testing is available as a "send out" (to a non-local lab). We are using said testing method at Chief Medical Officer Discretion, which includes all instance where no pre-transfusion ABO result is available.

2. Which staff/roles are considered a Qualified Health Care Professional who will make independent determinations of blood type? Would one of these Qualified Health Care Professionals include someone with blood banking/center background or transfusion medicine?

   Qualified Health Care Professionals who make independent determinations of blood type include Clinical Operations Managers (COM), Organ Allocation Coordinators (OAC), and Clinical Procurement Coordinators (CPC). Other roles are trained to the ABO verification process, but do not make the independent determinations.

   We do not recognize any members of our staff performing these roles as individuals with blood banking/center or transfusion medicine expertise. Indeterminate scenarios trigger a HARD STOP and Chief Medical Officer consult. External ABO-related expertise is then consulted as warranted for the scenario.

3. Have there been any updates to the CAP since CADN's last updated submission dated January 14th? If so, can you provide a summary of those updates?

   The following is a summary of updates since January 14th:

   - SE-P-011 ABO and Subtype Testing and Verification was finalized and went effective on 2/15/2021.

     It was revised on 5-26-2021 to include instructions for how to request and submit samples for ABO genotype testing (for ease of reference).

The procedure is again in revision to hardwire the running of molecular ABO when no pre-transfusion ABO result is available. [We currently require CMO consult in these scenarios; and the CMO then instructs our team to proceed with genotype testing. This revision retains the CMO consult; but automatically triggers the molecular test rather than waiting for the CMO to request it].

- On 5-26-21, we introduced a job aid SE-J-021 JOB AID – COMPLETING THE ORGAN VRL MOLECULAR ABO REQUISITION FORM. This, again, formalized the instructions for how to request molecular ABO for consistency and ease of reference.
- SE-P-014 HARD STOP PROCESS was finalized and went effective on 2-15-2021. It was revised on 5/26/2021 to include additional examples of when to use HARD STOP and assure consistent use in certain scenarios.
- ABO training curriculum was revised and deployed to applicable staff with a February 15th completion date. It includes scenario trainings and comprehension checkpoints. A revised version is in development and expected to deploy at the end of July or beginning of August.
- Our contracted testing lab is immediately notifying our team of any cancelled test in real time via direct phone call.

Please let us know if we can further clarify the above, or answer additional questions. We would also value any insights / best practices that improve this process.

Sincerely,